

**EPA REGISTRATION NUMBER 264-1081 – VOL. 1**

# ISB'S Front-end PRIA Completeness Screen

Draft 3; 10/25/07

E-SUB # 1046

EPA Receipt Date: 8/20/08		EPA Reg. Number: 264-RNIR		
	Check List Item	Yes	No	N/A
1	Has the <b>PRIA Fee been Paid</b> ; is a copy of the check or Pay.gov receipt included in the Submission Package?	X		
2	Is an <b>Application Form</b> (EPA Form 8570-1) Included in the Submission Package, is it completely filled out and signed including package type?	X		
3	Is a <b>Confidential Statement of Formula</b> (EPA Form 8570-29) Included in the Submission Package, is it completely filled out and signed (boxes 1-21)?	X		
4	Is a <b>Formulator's Exemption Statement</b> (EPA Form 8570-27) Included in the Submission Package?	X		
5	Is a <b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) Included in the Submission Package?	X		
6	Is a <b>Data Matrix</b> (EPA Form 8570-35) Included in the Submission Package?	X		
7	Is a <b>Label</b> Included in the Submission Package?	X		
8	Are <b>Data</b> Included in the Submission Package?	X		
9	Is the Submission an Amendment?		X	



# Material to be added to an e-Jacket/Jacket

Reg. No. 264-1081

Description: Agency ltr 5/27/11, immunotox review 5/5/11, bean sheet 11/29/10

1. ☐ Placement within the e-Jacket/jacket:
- ☐ Default: (chronological, top = newest)
  - ☐ File Location: (PDF page number, i.e., "before page 45")
- default = top is newest

2. ☐ Send to Data Extraction contractors this material:

- ☐ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer's Name: Marianne Lewis

Phone: 703-308-8043 Division: RD/IRB

Date: 5/27/11

This form was created on 5/27/2011



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION

MAY 27 2011

Jamin Huang  
Bayer CropScience  
2 T.W. Alexander Drive  
P.O. Box 12014  
Research Triangle Park, NC 27709

Subject: Submission of 28 Day Dietary Immunotoxicity data  
Sepresto 75 W  
EPA Registration No. 264-1081  
Submission dated November 29, 2010

Dear Mr. Huang:

The conditional data referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, is acceptable. A copy of the review is enclosed. Should you have any questions, please contact me at 703-308-8043 or [lewis.marianne@epa.gov](mailto:lewis.marianne@epa.gov).

Sincerely,

A handwritten signature in blue ink, appearing to read "Marianne Lewis".

Marianne Lewis  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY AND  
POLLUTION PREVENTION

05 MAY 2011

**MEMORANDUM**

**SUBJECT: Imidacloprid: Conditional Data (Immunotoxicity Data)**

**PC Code:** 129099

**Decision No.:** 442536

**Petition No.:** NA

**Risk Assessment Type:** Tox DER

**TXR No.:** 0053626

**MRID No.:** 48298701

**DP Barcode:** D384409

**Registration No.:** 264-1081

**Regulatory Action:** Section 3

**Case No.:** NA

**CAS No.:** 138261-41-3

**40 CFR:** 180.472

Ver. Apr. 08

**FROM:** Vincent Chen, Toxicologist  
Risk Assessment Branch III  
Health Effects Division, 7509P

05 MAY 2011

**THROUGH:** Whang Phang, Toxicologist  
Risk Assessment Branch III  
Health Effects Division, 7509P

**TO:** Venus Eagle, Product Manager  
Insecticide-Rodenticide Branch  
Registration Division, 7505P

This 28-day dietary immunotoxicity study in rats (MRID 48298701) has been classified as Acceptable / Guideline upon review and can be used in support of risk assessment. The DER is attached.



EPA Reviewer: Vincent Chen, M.S.  
Risk Assessment Branch 3, Health Effects Division (7509P)  
EPA Secondary Reviewer: Yung G. Yang, Ph.D.  
Risk Assessment Branch 3, Health Effects Division (7509P)

Signature: [Signature]  
Date: 05 MAY 2011  
Signature: [Signature]  
Date: 5/5/2011

Template version 02/06

TXR #: 0053626

**DATA EVALUATION RECORD**

**STUDY TYPE:** 28-Day Dietary Immunotoxicity Study - Rat  
OPPTS 870.7800

**PC CODE:** 129099**DP BARCODE:** D384409**TEST MATERIAL (PURITY):** Imidacloprid (98.5% a.i.)

**SYNONYMS:** N-[1-[(6-Chloro-3-pyridyl)methyl]-4,5-dihydroimidazol-2-yl]nitramide  
1-[(6-chloro-3-pyridinyl)methyl]-N-nitro-2-imidazolidinimine

**CITATION:** Kennel, P. (2010). Imidacloprid 28-Day Immunotoxicity Study in the Male Wistar Rat by Dietary Administration. Bayer S.A.S., Bayer Cropscience, 355, Rue Dostoievski BP 153, 06903 Sophia Antipolis Cedex, France. Laboratory Study Number: SA 09406, 05 November 2010. MRID: 48298701. Unpublished.

**SPONSOR:** Bayer Cropscience AG  
Alfred Nobel Str. 50, 40789 Monheim, Germany

**EXECUTIVE SUMMARY:**

In an immunotoxicity study (MRID 48298701) Imidacloprid (98.5% a.i., batch number: EDE0030814) was administered to male Wistar Rj:WI (IOPS HAN) rats (10/dose) through diet at dose levels of 0, 150, 600, or 2400 ppm (0, 11.7, 47.1, or 186 mg/kg/day, respectively). The positive control group consisting of 10 male Wistar Rj:WI (IOPS HAN) rats were administered 3.5 mg/kg/day cyclophosphamide daily via gavage. On Day 26, all test animals received a 0.5 mL intravenous injection of sheep red blood cells (SRBCs) at a concentration of  $5 \times 10^8$  cells/mL. On Day 30, blood samples (0.5 mL) were taken from all groups by puncture of the retro-orbital venous plexus. The level of SRBC IgM in response to antigen administration was determined with an Enzyme-Linked Immunosorbent Assay (ELISA). Other parameters evaluated were: clinical condition, mortality, body weight, body weight gain, food consumption, spleen weight, and thymus weight.

In the treated animals there were no treatment-related findings for clinical signs of toxicity and there were no unscheduled mortalities. At the 2400 ppm dose, the treatment-related effects observed were decreased body weight, body weight gain, food consumption and thymus weights.

The anti-SRBC IgM ELISA results indicate that there were no treatment-related effects on the quantity of anti-SRBC IgM concentrations in any treatment group when compared with the vehicle controls. There were no statistical differences in quantity of anti-SRBC IgM in any



treatment group when compared with the vehicle controls. A high inter-individual variability was noted in all the treatment groups as well as in the control group. Evaluation of individual animal data did not show any trend or distribution that would demonstrate significant suppression of anti-SRBC antibody response. The method of analysis for the anti-SRBC IgM ELISA was proven acceptable by the results from the cyclophosphamide positive control group, in which there was a near complete suppression of the antibody response to a challenge with SRBC.

The Natural Killer (NK) cells activity assay was not performed in this study. The decrease in thymus weight at the 2400 ppm was considered a secondary effect due to decreased body weight; the relative thymus weight was not significantly different from the control. In addition, the toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. Under HED guidance, NK cell activity assay is not required at this time.

**The systemic toxicity LOAEL was 2400 ppm (186 mg/kg/day) based on decreased body weight, body weight gain, and food consumption. The NOAEL was 600 ppm (47.1 mg/kg/day).**

**The NOAEL for anti-SRBC IgM response is 2400 ppm (186 mg/kg/day), the LOAEL was not established.**

This immunotoxicity study is classified acceptable/ guideline and satisfies the guideline requirement for an immunotoxicity study (OPPTS 870.7800) in rats.

**COMPLIANCE:**

Signed and dated GLP, Quality Assurance, and Data Confidentiality statements were provided.



**I. MATERIALS AND METHODS****A. MATERIALS:****1. Test Material:**

Imidacloprid

Description:

Technical, White Powder

Lot/Batch #:

EDE0030814

Purity:

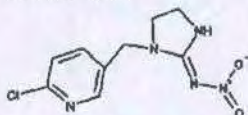
98.5% a.i.

Compound Stability:

Stable at 25 ± 5°C

CAS # of TGA:

138261-41-3

**2. Vehicle and Positive Control:**

Vehicle: Treated and Control Animals: Basal Diet

Positive Control: Cyclophosphamide (100.2% a.i., batch number: 097K1311) in sterilized water. Source: Sigma-Aldrich, USA

**3. Test Animals:**

Species:

Rat

Strain:

Wistar Rj: WI (IOPS HAN)

Age/Weight at Study Initiation:

Age: ~7 weeks old

Weight: 218-258 g

Source:

R. Janvier, Le Genest St Isle, France

Housing:

Individually in suspended, stainless steel, wire-mesh cages

Diet:

Certified rodent powdered and irradiated diet AC04CP1-10 *ad libitum*  
Scientific Animal Food and Engineering (Augy, France)

Water:

Filtered and softened municipal water *ad libitum*

Environmental Conditions:

Temperature: 20-24°C

Humidity: 40-70%

Air Changes: 10-15/hr

Photoperiod: 12 hrs dark / 12 hrs light

Acclimation Period:

12 days

**B. STUDY DESIGN:****1. In Life Dates:** 17 May 2010 – 15 June 2010**2. Animal Assignment:** Animals were assigned randomly to the test groups noted in Table 1.Table 1: Study Design<sup>a</sup>

Test Group	Dietary Concentration (ppm)	Dose to Animal (mg/kg/day)	# Male	# Female
Control	0	0	10	0
Low	150	11.7	10	0
Mid	600	47.1	10	0
High	2400	186	10	0
Positive Control	0	3.5 <sup>b</sup>	10	0

<sup>a</sup> Information was obtained from pages 18 and 26 of the study report<sup>b</sup> Dosed daily with 5 mL/kg cyclophosphamide via gavage for 28 days.



**3. Species and Gender Selection:**

The performing laboratory selected the male Wistar Rj: WI (IOPS HAN) rat based on the results from previous studies in Table 2 indicating that rats are more sensitive than mice and males are more sensitive than females.

Table 2: Species and Gender Comparison <sup>a</sup>				
Comparison	Study Type	Effect Observed	(mg/kg/day)	(mg/kg/day)
Males vs. Females	90-day dietary in rats	Decreased body weight	Male LOAEL: 61	Female LOAEL: 422
		Liver pathology	Male LOAEL: 300	Female LOAEL: >422
	Chronic dietary in rats	Decreased body weight	Male NOAEL: 16.9	Female NOAEL: 24.9
		Thyroid mineralization	Male LOAEL: 17	Female LOAEL: 73
Rats vs. Mice	90-day dietary in mice	Decreased body weight	Male: 391	Female: 3087
	Oncogenicity in mice	Decreased body weight	Male NOAEL: 208	Female NOAEL: 274
	90-day dietary	Decreased body weight	Male Rat: 61	Male Mouse: 391
	Chronic/Oncogenicity	Decreased body weight	Male Rat: 16.9	Male Mouse: 208

<sup>a</sup> Information was obtained from page 17 of the study report

**4. Dose Selection:** The dose levels were selected based on the results of previous subchronic and chronic toxicity studies.**5. Diet Preparation and Analysis:**

Diet was prepared at one time by mixing appropriate amounts of test substance with Certified rodent powdered and irradiated diet AC04CP1-10 and was stored at -18°C temperature. Homogeneity and stability were tested once during the study. During the study, samples of treated food were analyzed at all doses once for stability and concentration.

The analytical data indicated that the mixing procedure was adequate and the variation between nominal and actual dosages was acceptable (Table 3).

Table 3: Results of Diet Analysis <sup>a</sup>	
Homogeneity (% nominal concentration):	93-97%
Stability (% nominal concentration):	93-97% following storage for 28 days frozen and 14 days at room temperature
Concentration (% nominal concentration):	95-97%

<sup>a</sup> Information was obtained from pages 168, 170, and 171 of the study report

**6. Statistics:**

Statistical significance was judged at  $p \leq 0.05$ . Specific analyses were performed on the data collected as listed in Table 4.

Table 4: Statistical Analysis <sup>a</sup>	
Parameter	Statistical Algorithm
Terminal Body Weight Absolute and Relative Organ Weight	<p>Comparing negative and positive control groups</p> <p>If F test is significant Then use Modified t-test (2-sided test) Else use t-test (2-sided test)</p> <p>Comparing negative control and test substance groups for homogeneity</p> <p>If Bartlett test is significant Then use Kruskal-Wallis test If Kruskal-Wallis test is significant Then use Dunn test (2-sided test) Else use ANOVA test If ANOVA test is significant</p>



	Then use Dunnett test (2-sided test)
Body Weight Average Food Consumption per Day	<p><u>Comparing negative and positive control groups</u>            If F test is significant            Then transform data and use F test on transformed data            If F test on transformed data is significant            Then use Modified t-test (2-sided test)            Else use t-test on transformed data (2-sided test)            Else use t-test (2-sided test)</p> <p><u>Comparing negative control and test substance groups</u>            If Bartlett Test is significant            Then transform data and use Bartlett test on transformed data            If Bartlett test on transformed data is significant            Then use Kruskal-Wallis test            If Kruskal-Wallis test is significant            Then use Dunn test (2-sided test)            Else use ANOVA test on transformed data            If ANOVA test on transformed data is significant            Then use Dunnett test on transformed data (2-sided test)            Else use ANOVA test            If ANOVA test is significant            Then use Dunnett test (2-sided test)</p>
Immunological	<p><u>Comparing negative control and test substance groups</u>            If Kruskal-Wallis test is significant            Then use Dunn test (2-sided test)</p>

<sup>a</sup> Information was obtained from pages 21-24 of the study report

## C. METHODS:

### 1. Observations:

Animals were inspected twice daily (once daily on weekends or public holidays) for morbidity and mortality, once daily for clinical signs, and once a week a detail physical examination was conducted for signs of toxicity and mortality.

### 2. Body Weight:

Animals were weighed once at the start of treatment (i.e. Day 1), weekly thereafter, and prior to sacrifice.

### 3. Food Consumption and Compound Intake:

The weight of food supplied and of that remaining at the end of the food consumption period was recorded weekly for all animals during the treatment period. The weekly mean achieved dosage intake in mg/kg/day for each week and for Weeks 1-4 was calculated (except for the group exposed to the immunosuppressive agent cyclophosphamide) using the following formula:

$$\text{Achieved intake (mg/kg/day)} = \frac{\text{Dose level (ppm)} \times \text{Group mean food consumption (g/day) per week}}{\text{Group mean body weight (g) at end of week}}$$

### 4. Water Consumption: Water consumption was not quantified.

### 5. Sacrifice and Pathology:

On day 30, all animals from all groups were sacrificed by exsanguination while under deep anesthesia (isoflurane inhalation). The animals were not diet fasted prior to final sacrifice.



All animals were necropsied. The necropsy included the examinations of all major organs, tissues and body cavities. Macroscopic abnormalities were recorded by not sampled.

6. **Organ Weights:** The spleen and thymus weights were recorded.

7. **Sheep Red Blood Cell (SRBC)-Specific IgM Assay:**

On the day of injection, SRBCs were washed in phosphate buffered saline (PBS), counted using a cell counting instrument (Siemens Advia 120) and diluted in PBS to a final concentration of  $5 \times 10^8$  cells/mL. On day 26 after the start of treatment, all animals in all groups were immunized by intravenous injection in the tail vein (0.5 mL/animal) with SRBC. When necessary, prior to intravenous injection, animals were anesthetized with Isoflurane (Baxter, Maurepas, France).

On day 30, blood samples (0.5 mL) were taken from all groups by puncture of the retro-orbital venous plexus. The level of SRBC IgM in response to antigen administration was determined with an Enzyme-Linked Immunosorbent Assay (ELISA). Rat Anti-Sheep Red Blood Cell IgM ELISA kits from Life Diagnostics (West Chester, PA 19380, USA) were used.

## II. RESULTS:

### A. OBSERVATIONS:

1. **Clinical Signs of Toxicity:** There were no treatment-related findings observed.
2. **Mortality:** There were no unscheduled mortalities during the study.

### B. Body Weight and Body Weight Gain:

Treatment-related decreased body weight was observed at the 2400 ppm dose with the effects manifesting on Day 8 (-18.9%) and persisting to the end of the study (Table 5). Treatment-related decreased body weight gain was observed at 2400 ppm throughout treatment but the severity declined as the study progressed. For positive control group, mean body weights were reduced by 3-5% throughout the study and mean weight gains were reduced by 10-16%.

Table 5: Mean Body Weights and Body Weight Gains in Rats Treated with Imidacloprid or Cyclophosphamide <sup>a</sup>					
Males	Dose Group (ppm)				Cyclophosphamide
	0	150	600	2400	3.5 mg/kg/day
Time Point	Mean Body Weights (g) $\pm$ SD (% difference from control)				
Day 01	241 $\pm$ 9	240 $\pm$ 12 (-0.4)	241 $\pm$ 9 (0.0)	244 $\pm$ 7 (1.2)	242 $\pm$ 10 (0.0)
Day 08	296 $\pm$ 11	290 $\pm$ 20 (-2.0)	290 $\pm$ 15 (-2.0)	240 $\pm$ 11 (-18.9)**	288 $\pm$ 14 (-2.7)
Day 15	334 $\pm$ 13	325 $\pm$ 26 (-2.7)	328 $\pm$ 23 (-1.8)	265 $\pm$ 10 (-20.7)**	320 $\pm$ 14 (-4.2)**
Day 22	368 $\pm$ 16	360 $\pm$ 30 (-2.2)	363 $\pm$ 28 (-1.4)	295 $\pm$ 13 (-19.8)**	351 $\pm$ 15 (-4.6)**
Day 29	396 $\pm$ 22	389 $\pm$ 29 (-1.8)	390 $\pm$ 32 (-1.5)	320 $\pm$ 21 (-19.2)**	378 $\pm$ 16 (-4.5)
Time Interval	Mean Body Weight Gain (g/day) $\pm$ SD (% difference from control)				
Days 01-08	7.8 $\pm$ 0.8	7.1 $\pm$ 1.2 (-9.0)	6.9 $\pm$ 1.1 (-11.5)	-0.5 $\pm$ 1.9 (-106.4)**	6.6 $\pm$ 0.9 (-15.4)
Days 08-15	5.5 $\pm$ 1.4	5.1 $\pm$ 1.2 (-7.3)	5.5 $\pm$ 1.1 (0.0)	3.5 $\pm$ 1.7 (-36.4)**	4.6 $\pm$ 1.0 (-16.4)
Days 15-22	4.9 $\pm$ 0.7	4.9 $\pm$ 0.7 (0.0)	5.0 $\pm$ 0.9 (2.0)	4.3 $\pm$ 1.2 (-12.2)	4.4 $\pm$ 0.7 (-10.2)
Days 22-29	3.9 $\pm$ 1.1	4.2 $\pm$ 0.5 (7.7)	3.8 $\pm$ 0.8 (-2.6)	3.6 $\pm$ 1.6 (-7.7)	4.0 $\pm$ 0.9 (2.5)

n= 10 animals per dose group

<sup>a</sup> Information was obtained from pages 47, 49, 52, and 54 of the study report



\*\* p&lt;0.01

**C. FOOD CONSUMPTION AND COMPOUND INTAKE:****1. Food Consumption:**

Treatment-related decreased food consumption was observed throughout treatment at the 2400 ppm dose, but the severity declined as the study progressed (Table 6).

Table 6: Mean Foods Consumption in Rats Treated with Imidacloprid <sup>a</sup>				
Males	Dose Group (ppm)			
	0	150	600	2400
Time Interval	Mean Food Consumption (g/day) $\pm$ SD (% difference from control)			
Days 01-08	25.4 $\pm$ 1.3	24.3 $\pm$ 1.4 (-4.3)	23.2 $\pm$ 1.9 (-8.7)	13.8 $\pm$ 3.4 (-45.7)**
Days 08-15	25.5 $\pm$ 1.5	25.0 $\pm$ 1.7 (-2.0)	25.7 $\pm$ 2.1 (0.8)	19.5 $\pm$ 3.9 (-23.5)**
Days 15-22	25.6 $\pm$ 2.3	24.8 $\pm$ 2.1 (-3.1)	26.1 $\pm$ 2.1 (2.0)	20.4 $\pm$ 2.7 (-20.3)**
Days 22-29	25.2 $\pm$ 2.0	25.0 $\pm$ 1.7 (-0.8)	26.1 $\pm$ 1.9 (3.6)	20.8 $\pm$ 2.9 (-17.5)**

n= 10 animals per dose group

<sup>a</sup> Information was obtained from page 62 of the study report

\*\* p&lt;0.01

**2. Compound Intake:** The achieved dosages in the test groups are reported in Table 7.

Table 7: Mean Compound Intake for Rats Treated with Imidacloprid <sup>a</sup>				
Males	Dose Group (ppm)			
	0	150	600	2400
Time Interval	Group Mean Compound Intake (mg/kg/day)			
Days 01-08	0	13.7	53.5	201
Days 08-15	0	12.0	48.6	197
Days 15-22	0	11.0	44.6	179
Days 22-29	0	10.3	41.7	166
Days 01-29	0	11.7	47.1	186

<sup>a</sup> Information was obtained from page 66 of the study report**3. Food Efficiency:** Food efficiency was not determined.**D. WATER CONSUMPTION:** Water consumption was not determined.**E. ORGAN WEIGHTS:**

A treatment-related decrease in absolute thymus weight (-28.1%) and an increase in relative spleen weight (19.1%) was observed at the 2400 ppm dose (Table 8). In the absence of immunosuppressive findings, these effects were not considered toxicologically relevant.

Table 8: Organ Weight Results for Rats Treated with Imidacloprid <sup>a</sup>				
Males	Dose Group (ppm)			
	0	150	600	2400
	Mean Terminal Weight (g) $\pm$ SD (% difference from control)			
Body Weight	400.7 $\pm$ 21.5	393.7 $\pm$ 29.8 (-1.8)	394.0 $\pm$ 32.9 (-1.7)	325.0 $\pm$ 19.6 (-18.9)
Spleen	1.086 $\pm$ 0.154	1.116 $\pm$ 0.150 (2.8)	1.090 $\pm$ 0.151 (0.4)	1.048 $\pm$ 0.130 (-3.5)
Thymus	0.857 $\pm$ 0.219	0.846 $\pm$ 0.139 (-1.3)	0.819 $\pm$ 0.136 (-4.4)	0.616 $\pm$ 0.089 (-28.1)**
	Mean Relative Organ Weight (% Body Weight) $\pm$ SD (% difference from control)			
Spleen	0.2706 $\pm$ 0.0320	0.2835 $\pm$ 0.0305 (4.8)	0.2776 $\pm$ 0.0384 (2.6)	0.3223 $\pm$ 0.0318 (19.1)**
Thymus	0.2133 $\pm$ 0.0497	0.2147 $\pm$ 0.0295 (0.7)	0.2096 $\pm$ 0.0422 (-1.7)	0.1899 $\pm$ 0.0269 (-11.0)

n= 10 animals per dose group unless otherwise noted



- \* Information was obtained from page 74 of the study report  
\*  $p < 0.01$

## F. IMMUNOTOXICITY TESTS:

### 1. Anti-SRBC IgM Enzyme-Linked Immunosorbent Assay (ELISA):

The results of the anti-SRBC IgM ELISA did not indicate any treatment-related immunosuppressive effects (Table 9). There were no statistical differences in quantity of anti-SRBC IgM in any treatment group when compared with the vehicle controls. A high inter-individual variability was noted in all the treatment groups as well as in the control group. Evaluation of individual animal data did not show any trend or distribution that would demonstrate significant suppression of anti-SRBC antibody response (Figure 1). The positive control group demonstrated a statistical decrease in antibody concentration as compared to the vehicle controls.

Table 9: Anti-SRBC IgM ELISA Results for Rats Treated with Imidacloprid <sup>a</sup>	
Dose Group (ppm)	Mean Anti-SRBC IgM (U/mL) $\pm$ SD (% difference from negative control)
Negative Control (0) [n=9]	17340 $\pm$ 14985
150	10541 $\pm$ 5232 (-39.2)
600	8919 $\pm$ 4743 (-48.6)
2400	10775 $\pm$ 7899 (-37.9)
Positive Control <sup>b</sup>	916 $\pm$ 1003 (-94.7)**

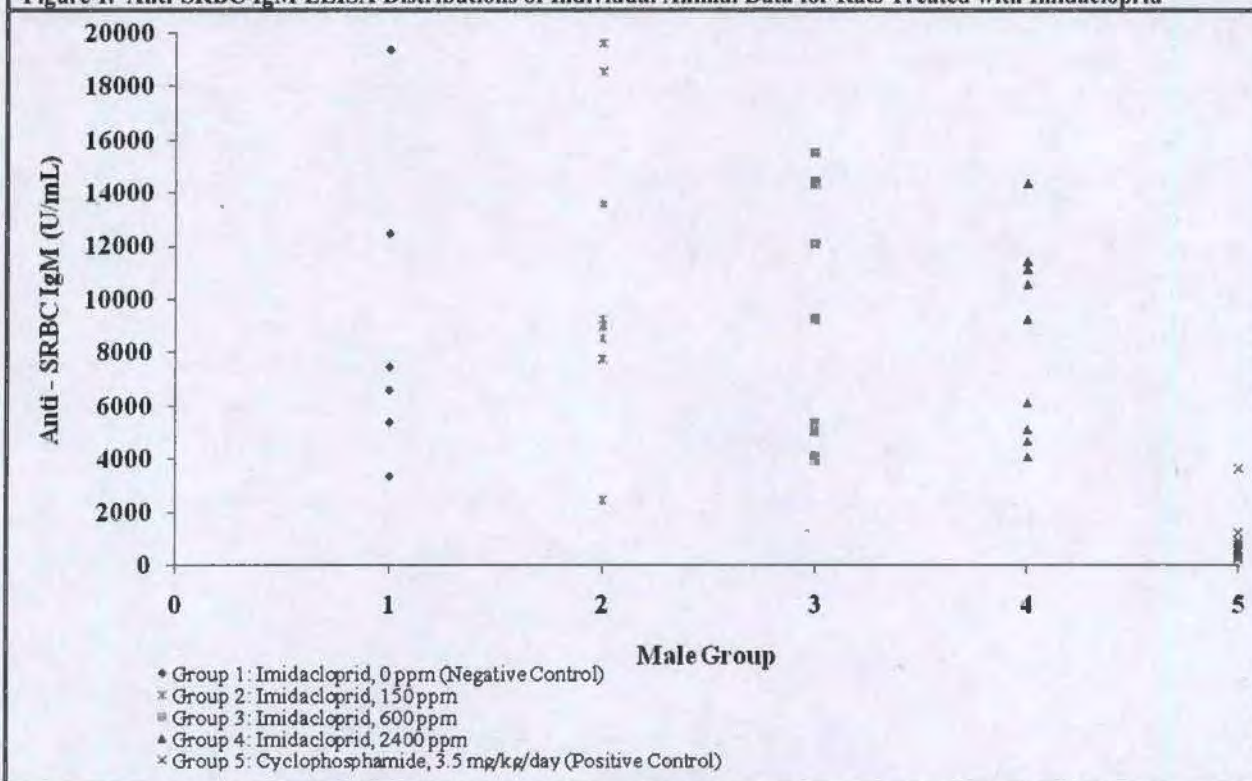
n= 10 animals per dose group unless otherwise noted

<sup>a</sup> Information was obtained from pages 69 and 71 of the study report

<sup>b</sup> Cyclophosphamide (3.5 mg/kg/day) administered once daily via gavage

\*\*  $p < 0.01$

Figure 1. Anti-SRBC IgM ELISA Distributions of Individual Animal Data for Rats Treated with Imidacloprid<sup>a</sup>



<sup>a</sup> Information was obtained from pages 100 and 101 of the study report



2. **Natural Killer (NK) Cell Activity Assay:** Assay was not performed.

**G. SACRIFICE AND PATHOLOGY:**

Microscopic pathology was not evaluated. There were no toxicologically relevant gross pathological findings observed.

**III. DISCUSSION AND CONCLUSIONS:**

**A. INVESTIGATORS' CONCLUSIONS:**

Imidacloprid dietary administration at dose levels of 150, 600, and 2400 ppm to male Wistar rats for at least 28 days induced no treatment-related mortalities. In the control group, body weight parameters and food consumption were not affected by the antigen (SRBC) injection. Immunization of the control male rats resulted in a robust antibody response on Study Day 30. This confirmed the sensitization of the animals and the validity of the study design.

No immunotoxic properties were detected for imidacloprid in male Wistar rats. The dose level at 2400 ppm (corresponding to 186 mg/kg/day) is considered to exceed the Maximum Tolerated Dose in terms of general toxicity and to be a No Observed Effect Level for the immunotoxicological parameters investigated.

**B. REVIEWER'S COMMENTS:**

In the treated animals there were no treatment-related findings for clinical signs of toxicity and there were no unscheduled mortalities.

At the 2400 ppm dose, the treatment-related effects observed were decreased body weight, body weight gain, food consumption and thymus weights.

The anti-SRBC IgM ELISA results indicate that there were no treatment-related effects on the quantity of anti-SRBC IgM concentrations in any treatment group when compared with the vehicle controls. The method of analysis for the anti-SRBC IgM ELISA was proven acceptable by the results from the cyclophosphamide positive control group, in which there was a near complete suppression of the antibody response to a challenge with SRBC. Additionally, the distribution of individual animal data for the treatment and control groups demonstrates that imidacloprid exposure does not lead to significant suppression of anti-SRBC response.

The Natural Killer (NK) cells activity assay was not performed in this study. The decrease in thymus weight at the 2400 ppm was considered a secondary effect due to decreased body weight; the relative thymus weight was not significantly different from the control. The toxicology database for imidacloprid does not show any evidence of treatment-related effects on the immune system. The overall weight of evidence suggests that this chemical does not directly target the immune system. Under HED guidance, NK cells activity assay is not required at this time.

The systemic toxicity LOAEL was 2400 ppm (186 mg/kg/day) based on decreased body weight, body weight gain, and food consumption. The NOAEL was 600 ppm (47.1



mg/kg/day).

The NOAEL for anti-SRBC response is 2400 ppm (186 mg/kg/day), the LOAEL was not established.

C. STUDY DEFICIENCIES: No significant major deficiency was noted.



# DATA PACKAGE BEAN SHEET

Date: 27-May-2011

Page 1 of 2

Decision #: 442536

DP #: (384409)

NON PRIA

Parent DP #:

Submission #: 885992

## \*\*\* Registration Information \*\*\*

Registration: **264-1081 - Sepresto 75 WS**

Company: **264 - BAYER CROPSCIENCE LP**

Risk Manager: **RM 01 - Venus Eagle - (703) 308-8045 Room# PY1 S-7228**

Risk Manager Reviewer: **Kable Davis KDAVIS5**

Sent Date: **22-Nov-2010**

Calculated Due Date: **09-Mar-2011**

Edited Due Date: \_\_\_\_\_

Type of Registration: **Product Registration - Section 3**

Action Desc: **(575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE**

Ingredients: **044309, Clothianidin(56.25%)**

**129099, Imidacloprid(18.75%)**

## \*\*\* Data Package Information \*\*\*

Expedite: ☐ Yes ☒ No

Date Sent: **29-Nov-2010**

Due Back: \_\_\_\_\_

DP Ingredient: **044309, Clothianidin**

**129099, Imidacloprid**

DP Title: **Conditional Data (Immunotoxicity Data)**

CSF Included: ☐ Yes ☒ No

Label Included: ☐ Yes ☒ No

Parent DP #: \_\_\_\_\_

### Assigned To

### Date In

### Date Out

Organization: **HED / RAB1**

**29-Nov-2010**

**05-May-2011**

Last Possible Science Due Date: **29-Dec-2010**

Team Name: \_\_\_\_\_

Science Due Date: \_\_\_\_\_

Reviewer Name: \_\_\_\_\_

Sub Data Package Due Date: \_\_\_\_\_

Contractor Name: \_\_\_\_\_

## \*\*\* Studies Sent for Review \*\*\*

Printed on Page 2

## \*\*\* Additional Data Package for this Decision \*\*\*

No Additional Data Packages

## \*\*\* Data Package Instructions \*\*\*

Attention Reviewer: As required by the registration notice dated April 28, 2010, Bayer has submitted an immunotoxicity study for imidacloprid. This data was also a condition of registration per Agency letter dated January 14, 2010 for EPA Reg. No. 432-1483. I will also include a copy of the cover letter. If you have any questions or need anything else, please let me know. Thanks for all your help!.....Bo



MRID	MRID Status	Citation Reference	Guideline
48298701	Acceptable/Guideline	Kennel, P. (2010) Imidacloprid: 28-Day Immunotoxicity Study in the Male Wistar Rat by Dietary Administration. Project Number: SA/09406, LYNX/PSI/N/TXNTL079. Unpublished study prepared by Bayer Cropscience. 196 p.	870.7800/Immunotoxicity





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

Jamin Huang, PhD  
Bayer CropScience  
2 T.W. Alexander Drive  
P.O. Box 12014  
Research Triangle Park, NC 27709

NOV 4 2010

Dear Dr. Huang:

Subject: Condition of Registration; Frozen Stability Data for Spinach and Tomatoes  
Sepresto 75 WS  
EPA Registration No. 264-1081  
Date Submitted: August 2, 2010

The Agency has reviewed the submitted Frozen Storage Stability of Clothianidin in Spinach and Tomatoes study (MRID 48170101) required by the Registration Notice dated April 28, 2010 for the product referenced above. The study was deemed acceptable and has adequately fulfilled the data requirement. For more detail, please see attached Agency review (D382140).

A similar Agency letter will be sent to Valent U.S.A. Corporation regarding the corresponding clothianidin technical product (EPA Reg. No. 59639-173). Should you have any questions, please contact Kable Bo Davis at (703) 306-0415 or [davis.kable@epa.gov](mailto:davis.kable@epa.gov).

Sincerely yours,

A handwritten signature in cursive script that reads "Venus Eagle".

Venus Eagle  
Product Manager 901)  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure- Agency Review (D382140)





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
CHEMICAL SAFETY AND  
POLLUTION PREVENTION**MEMORANDUM****Date:** 29 October 2010**Subject:** Clothianidin. Spinach and Tomato Storage Stability Studies, Submitted as Supplementary Residue Data Pursuant to Conditions of Registration in HED Human Health Risk Assessment of 13 August 2009 (D357034).**PC Code:** 044309  
**MRID Number:** 48170101  
**Petition Number:** NA  
**Assessment Type:** NA  
**TXR Number:** NA  
**Decision Number:** 438878**DP Barcode:** D382140  
**Registration Number:** 264-1081  
**Regulatory Action:** Amended Section 3  
**Registration Case Number:** NA  
**CAS Number:** 210880-92-5  
**40 CFR:** §180.586**From:** William T. Drew, Chemist *WTDrew*  
Registration Action Branch II (RAB2)  
Health Effects Division (HED), 7509P**Through:** Michael A. Doherty, PhD, Senior Chemist *Michael A Doherty*  
RAB2/HED, 7509P**To:** Kable Davis and Venus Eagle, RM Team 1  
Insecticide/Rodenticide Branch (IRB)  
Registration Division (RD), 7505P



## Background

Bayer CropScience has submitted a storage stability study with clothianidin in spinach and tomatoes in response to data deficiencies identified during HED's review of tolerance petitions #8F7413 and 8F7416 (*Clothianidin: Human Health Risk Assessment for Proposed Seed Treatment Uses on Root and Tuber Vegetables (Group 1), Bulb Vegetables (Group 3), Leafy Green Vegetables (Group 4A), Brassica Leafy Vegetables (Group 5), Fruiting Vegetables (Group 8), Cucurbit Vegetables (Group 9), and Cereal Grains (Group 15, except rice).*; D357034; M.A. Doherty; 13 August 2009). The data deficiency was cited in 10.2 of Doherty's risk assessment memorandum as follows:

**The final reports depicting the frozen storage stability of clothianidin in spinach and tomatoes are required for evaluation by HED. Submission of this report should be a condition of registration.**

The study demonstrated that residues of clothianidin are stable in spinach and tomatoes when stored frozen ( $\leq 0^{\circ}\text{C}$ , with the exception of four days when the freezer's temperature was a maximum of  $7.2^{\circ}\text{C}$ ) for up to 28 months (847 days).

HED has reviewed the submitted study, and concluded that it is acceptable for both scientific and regulatory purposes.

## Regulatory Conclusion

The spinach and tomato storage stability data deficiency (identified during HED's review of Bayer CropScience's proposed use of clothianidin on spinach and tomatoes, as requested in tolerance petitions #8F7413 and 8F7416) has been resolved.



Bayer CropScience



August 2, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

**ATTENTION:** Kable Bo Davis (Acting PM 07, RD, Insecticide-Rodenticide Branch)

**Re: Submission of a Report of Frozen Storage Stability of Clothianidin in Spinach and Tomatoes**

**Clothianidin Technical (EPA Reg. No.: 10308-32)  
Sepresto 75 WS (EPA Reg. No. 264-1081)**

Dear Mr. Davis,

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Bayer CropScience is herein submitting a report of the frozen storage stability of clothianidin in spinach and tomatoes, as requested in your January 29, 2010 approval letter of a clothianidin technical label amendment. This report is to support the registration of Sepresto 75 WS (EPA Reg. No. 264-1081) submitted by Bayer CropScience.

Please contact me at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

Jamin Huang, Ph.D.  
Senior Regulatory Manager



M-387075-01-1



Bayer CropScience



**TRANSMITTAL DOCUMENT**

**Clothianidin**

**Clothianidin Update for SEPRESTO Registration**

**Requested in the Agency's January 29, 2010 approval letter for Clothianidin Technical  
(EPA Reg. No. 10308-32)**

**Transmittal Date**

August 2, 2010

Company Official:

Company Name:

Bayer CropScience

Company Contact:

Jamin Huang

Company Telephone:

+1 919 549 2634

2 T.W. Alexander Drive  
RTP, NC 27709  
USA



M-387191-01-1



## **BIBLIOGRAPHY OF SUBMITTED DATA**

<b>Study No.</b>	<b>Study</b>	<b>Guideline No.</b>	<b>EPA MRID No.</b>
	860 Residue Chemistry		
	860.1380 Frozen Storage Stability in Tomato & Spinach Matrices		
1	Brunghardt, J. N.; Storage stability of clothianidin in tomato and spinach matrices; Bayer CropScience LP, Stilwell, KS, USA; Report No.: RATIY019; Document No.: M-356812-01-1; October 02, 2009; Pages: 62	860.1380	48170101





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 23, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

SUE-CHI SHEN  
VALENT U.S.A. CORPORATION  
SUMITOMO CHEMICAL COMPANY, LTD.  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596-8025

PRODUCT NAME: Clothianidin Technical  
COMPANY NAME: SUMITOMO CHEMICAL COMPANY, LTD.  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 10308-32  
EPA RECEIPT DATE: 08/06/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

*P. K. Moshe*  
Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



pm 1

# Fee for Service

{8808060~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☒ Studies?    ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S- 880806

EPA File Symbol/Reg. No.

10308-32

Pin-Punch Date:

8/6/2010

☒ This item is NOT subject to FFS action.

## Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_\_

## Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: Steve Schaible

Date: 8/29/10

Remarks:

E-SUBMISSION





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

August 20, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

VALENT U.S.A. CORPORATION  
SUMITOMO CHEMICAL COMPANY, LTD.  
1600 RIVIERA AVENUE, SUITE 200  
WALNUT CREEK, CA 94596-8025

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 06-AUG-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



E-Submission



**Memorandum**

10308-32

Date: 8 / 20 / 10

To: pm 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission

Conditional data

- e Submission package  
~~10308-32~~



Bayer CropScience



April 30, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

ATTENTION: Kable Bo Davis (Acting PM 07, RD)

**Re: Final Printed Label for Sepresto 75 WS  
(EPA Reg. No. 264-1081)**

Dear Mr. Davis,

In compliance with the requirements in the April 28, 2010 Notice of Registration for Sepresto 75 WS and your April 29, 2010 approval letter (to add carrot), we are herein submitting one copy of the final printed label for Sepresto 75 WS dated April 29, 2010 for your record.

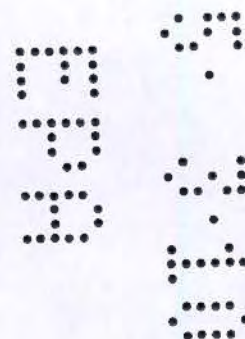
Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

Jamin Huang, Ph.D.  
Senior Regulatory Manager

Attachment

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000





# Sepresto 75 WS

APR 29 2010

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable and cereal seed, or as a potato seed piece treatment for the control of listed insect pests.

## ACTIVE INGREDIENTS:

Clothianidin.....56.25%  
Imidacloprid.....18.75%

OTHER INGREDIENTS: .....25.00%

TOTAL.....100.00%

E.P.A. Reg. No. 264-1081

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

For **MEDICAL And TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577  
For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

## FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>Take off contaminated clothing.</li><li>Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>Immediately call a poison control center or doctor for treatment advice.</li><li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>Have person sip a glass of water if able to swallow.</li><li>Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>
For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.	

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.**

**Read entire label before using this product.**

For use in commercial seed treaters only, with the exception of application to cereal grain crops (Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat), which may be made either by commercial seed treatment or as an end-use seed treatment on agricultural establishments immediately before planting, and with the exception of application to potato, which may be made on agricultural establishments using a seed dust metering applicator to seed-pieces immediately before planting. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All vegetable and cereal grain seed treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## FOR EARLY SEASON PROTECTION AGAINST LISTED INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

## ROOT VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Carrot	Carrot rust fly	0.06 to 0.12	0.002 to 0.0042
		(contains 0.0338 to 0.0675 g ai clothianidin and 0.0112 to 0.0225 g ai of imidacloprid per 1,000 seed)	(contains 0.0011 to 0.0024 oz ai clothianidin and 0.00036 to 0.00079 oz ai imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.



## BULB VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1000 seed	Ounces of Sepresto 75 WS per 1000 seed
Onion (bulb)	Onion maggot	0.21 to 0.32	0.0074 to 0.011
	Seedcorn maggot	(contains 0.118 to 0.18 g ai clothianidin and 0.039 to 0.06 g ai of imidacloprid per 1,000 seed)	(contains 0.0042 to 0.006 oz ai clothianidin and 0.0014 to 0.0020 oz ai of imidacloprid per 1000 seed)
	Thrips		
Leek	Onion maggot	0.36	0.0126
	Seedcorn maggot	(contains 0.20 g ai clothianidin and 0.0675 g ai of imidacloprid per 1,000 seed)	(contains 0.0071 oz ai clothianidin and 0.0024 oz ai of imidacloprid per 1,000 seed)
	Thrips		
Onion (bunching)		0.160 to 0.188 (contains 0.09 to 0.106 g ai clothianidin and 0.03 to 0.035 g ai of imidacloprid per 1,000 seed)	0.0056 to 0.0065 (contains 0.0032 to 0.0037 oz ai clothianidin and 0.001 to 0.0012 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## BRASSICA (COLE) LEAFY VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Broccoli	Aphids	2.12	0.074
	Flea beetle	(contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	(contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## CROPS OF CEREAL GRAINS EXCEPT RICE:

**Crops of Crop Group 15 except Rice including:** Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat

To provide early season protection of seedlings against injury by aphids (including Bird cherry-oat, English grain, Greenbug, and Russian wheat aphid), Hessian fly, apply at 41.3 g to 124 g of formulated product per 100 kg of seed (0.66 oz to 2.0 oz/100 lb of seed) prior to planting as a slurry treatment. Low use rate for "wireworm-only" protection: Sepresto 75 WS applied at 6.7 – 13.3 g per 100 kg seed (0.11 oz to 0.21 oz/100 lb of seed) offers suppression of wireworm activity on seed and young seedlings. For maximum effectiveness, treat seed uniformly. Use the higher rate to provide increased length of protection and from heavy insect pressure and from wireworms, and to reduce potential spread of Barley yellow dwarf virus due to aphid vectors.

## POTATO:

To aid in control of insects including aphids, Colorado potato beetle, flea beetle, potato leafhopper, and psyllids, apply at 11.11 to 22.22 grams of product per 100 kg (0.18 oz to 0.35 oz/100 lb of seed) of cut seed-pieces. To reduce damage to seed pieces caused by wireworms (*Limoni* sp., and *Melanotus* sp.) apply 22.22 grams of Sepresto 75 WS per 100 kg of cut seed-pieces. Apply using a seed dust metering applicator so that cut seed-pieces are thoroughly covered with the mixture. Thoroughly clean and sanitize cutting machines, knives, trays, tables, barrels, equipment, trucks, and planters before cutting and planting seed pieces. Plant seed-pieces as soon as possible after cutting and treating in accordance with the recommendations of your local extension potato specialist.

## ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted



immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

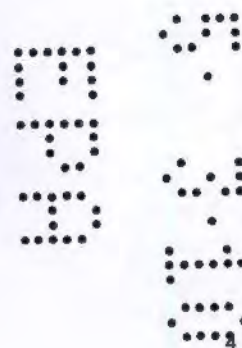
## **LABELING OF TREATED SEED**

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.





## IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

### NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

### NET CONTENTS:

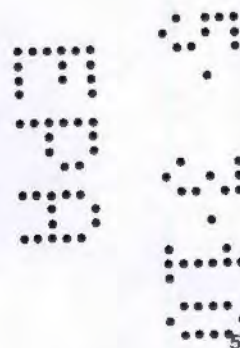
Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS (MASTER) Approved 04/28/10





## Sub Label: For Water Soluble Package

# Sepresto 75 WS

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable for the control of listed insect pests.

#### ACTIVE INGREDIENTS:

Clothianidin.....	56.25%
Imidacloprid.....	18.75%

OTHER INGREDIENTS: .....	25.00%
--------------------------	--------

TOTAL .....	100.00%
-------------	---------

E.P.A. Reg. No. 264-1081

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577  
For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

### FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>Take off contaminated clothing.</li><li>Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>Immediately call a poison control center or doctor for treatment advice.</li><li>Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>Have person sip a glass of water if able to swallow.</li><li>Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>Call a poison control center or doctor for treatment advice.</li></ul>
For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>NOTE TO PHYSICIAN:</b> No specific antidote is available. Treat the patient symptomatically.	

### PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read entire label before using this product.**

For use in commercial seed treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All seeds treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## MIXING PROCEDURES

Apply Sepresto 75 WS water soluble bag as a water-based slurry utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease control. Thoroughly mix the recommended amount of Sepresto 75 WS into the required amount of water prior to adding flowable or liquid solution to the treater.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container.

### OUTER PACKAGING

Outer packaging of this product is secondary packaging to contain water soluble plastic bags. Thoroughly rinse any soluble powder residue into application equipment; then offer for recycling if available or dispose of in a sanitary landfill.

### WATER SOLUBLE BAGS

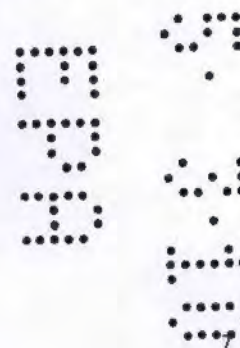
Allow sufficient time for bags to dissolve before use. There is no container disposal once the bags have dissolved.

## FOR EARLY SEASON PROTECTION AGAINST LISTED INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

Each water soluble bag contains 4 oz (0.25 lb) of Sepresto 75 WS.





**LEAFY GREEN VEGETABLES**

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Lettuce (head)	Leafminer (suppression)  Aphids	One bag to treat 80,000 seeds (Equivalent to 1.42 grams of Sepresto 75 WS per 1,000 seed which contains 0.798 g ai clothianidin and 0.266 g ai of imidacloprid per 1,000 seed)	One bag to treat 80,000 seeds (Equivalent to 0.05 ounces of Sepresto 75 WS per 1,000 seed which contains 0.028 oz ai clothianidin and 0.0094 oz ai of imidacloprid per 1,000 seed)
Lettuce (leaf)		One bag to treat 100,000 seeds (Equivalent to 1.14 grams of Sepresto 75 WS per 1,000 seed which contains 0.64 g ai clothianidin and 0.214 g ai of imidacloprid per 1,000 seed)	One bag to treat 100,000 seeds (Equivalent to 0.04 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0225 oz ai clothianidin and 0.0075 oz ai of imidacloprid per 1,000 seed)

**Restrictions**

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

**BRASSICA (COLE) LEAFY VEGETABLES**

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Cabbage	Aphids  Flea beetle	One bag to treat 54,000 seeds (Equivalent to 2.12 grams of Sepresto 75 WS per 1,000 seed which contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	One bag to treat 54,000 seeds (Equivalent to 0.074 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)

**Restrictions**

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

**ROTATIONAL CROPS:**

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

**LABELING OF TREATED SEED**

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

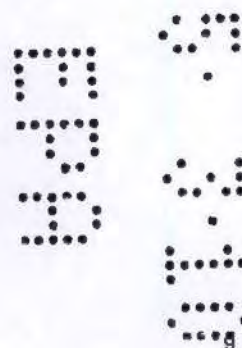
- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.



- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

#### **WATER SOLUBLE BAG RESTRICTIONS**

- Do not sell individual water soluble bags.
- Do not handle inner package with wet hands or wet gloves.
- Do not allow packages to become wet prior to application.
- Handle outer container carefully to prevent breakage of inner water soluble bags.
- Always reseal outer container in a manner that protects remaining bags from moisture.
- Do not remove the water soluble bags from the container except for immediate use.
- Use the entire contents of a water soluble bag, do not break open to use partial contents of water soluble bags.





## IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

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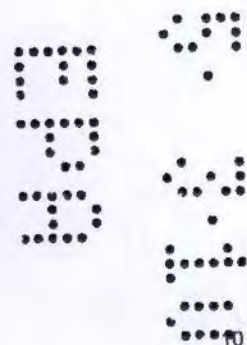
Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS Sub (MASTER) Approved 04/29/10





Label dated 07/29/2010 is not processed.

Label dated \_\_\_\_\_ is processed

CSF dated \_\_\_\_\_ is not processed.

CSF dated \_\_\_\_\_ is processed.

Jacket received date 06/28

Jacket location \_\_\_\_\_



# Material to be added to an e-Jacket/Jacket

Reg. No. 264-1081

Decision # 432717

Description:

new stamped label

1. Placement within the e-Jacket/jacket:

- ☐ Default: (chronological, top = newest)
- ☐ File Location: (eg. "before page 45 in .pdf")

2. ☒ Send to Data Extraction contractors this material:

- ☒ Newly stamped accepted label
- ☐ Notification
- ☐ New CSF
- ☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer: Xle B...

Division: RD

Phone: 306-0415

Date: 6-25-10





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Jamin Huang  
Bayer CropScience  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709

APR 29 2010

Dear Dr. Huang:

Subject: Labeling Amendment; Addition of Carrot  
Sepresto 75 WS  
EPA Registration No. 264-1081  
Date Submitted: April 29, 2010

The labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act, as amended, is acceptable. A stamped copy is enclosed for your records. Please submit one (1) final printed copy for the above mentioned label before releasing the product for shipment. If you have any questions regarding this label, please contact Kable Bo Davis at (703) 306-0415 or [davis.kable@epa.gov](mailto:davis.kable@epa.gov).

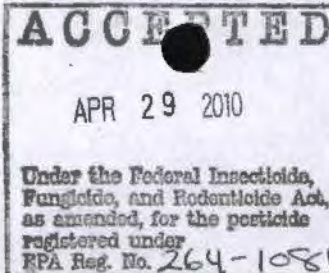
Sincerely yours,

A handwritten signature in cursive script that reads "Venus Eagle".

Venus Eagle  
Product Manager (01)  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

Enclosure- Stamped Label





# Sepresto 75 WS

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable and cereal seed, or as a potato seed piece treatment for the control of listed insect pests.

## ACTIVE INGREDIENTS:

Clothianidin.....56.25%  
Imidacloprid.....18.75%

OTHER INGREDIENTS: .....25.00%

TOTAL 100.00%

E.P.A. Reg. No. 264-1081

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577  
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

## FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor for treatment advice.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
For MEDICAL Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
NOTE TO PHYSICIAN: No specific antidote is available. Treat the patient symptomatically.	

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read entire label before using this product.**

For use in commercial seed treaters only, with the exception of application to cereal grain crops (Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat), which may be made either by commercial seed treatment or as an end-use seed treatment on agricultural establishments immediately before planting, and with the exception of application to potato, which may be made on agricultural establishments using a seed dust metering applicator to seed-pieces immediately before planting. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All vegetable and cereal grain seed treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## FOR EARLY SEASON PROTECTION AGAINST LISTED INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

## ROOT VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Carrot	Carrot rust fly	0.06 to 0.12	0.002 to 0.0042
		(contains 0.0338 to 0.0675 g ai clothianidin and 0.0112 to 0.0225 g ai of imidacloprid per 1,000 seed)	(contains 0.0011 to 0.0024 oz ai clothianidin and 0.00036 to 0.00079 oz ai imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.



## BULB VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1000 seed	Ounces of Sepresto 75 WS per 1000 seed
Onion (bulb)	Onion maggot	0.21 to 0.32	0.0074 to 0.011
	Seedcorn maggot	(contains 0.118 to 0.18 g ai clothianidin and 0.039 to 0.06 g ai of imidacloprid per 1,000 seed)	(contains 0.0042 to 0.006 oz ai clothianidin and 0.0014 to 0.0020 oz ai of imidacloprid per 1000 seed)
	Thrips		
Leek	Onion maggot	0.36	0.0126
	Seedcorn maggot	(contains 0.20 g ai clothianidin and 0.0675 g ai of imidacloprid per 1,000 seed)	(contains 0.0071 oz ai clothianidin and 0.0024 oz ai of imidacloprid per 1,000 seed)
	Thrips		
Onion (bunching)		0.160 to 0.188 (contains 0.09 to 0.106 g ai clothianidin and 0.03 to 0.035 g ai of imidacloprid per 1,000 seed)	0.0056 to 0.0065 (contains 0.0032 to 0.0037 oz ai clothianidin and 0.001 to 0.0012 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## BRASSICA (COLE) LEAFY VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Broccoli	Aphids	2.12	0.074
	Flea beetle	(contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	(contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## CROPS OF CEREAL GRAINS EXCEPT RICE:

**Crops of Crop Group 15 except Rice including:** Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat

To provide early season protection of seedlings against injury by aphids (including Bird cherry-oat, English grain, Greenbug, and Russian wheat aphid), Hessian fly, apply at 41.3 g to 124 g of formulated product per 100 kg of seed (0.66 oz to 2.0 oz/100 lb of seed) prior to planting as a slurry treatment. Low use rate for "wireworm-only" protection: Sepresto 75 WS applied at 6.7 – 13.3 g per 100 kg seed (0.11 oz to 0.21 oz/100 lb of seed) offers suppression of wireworm activity on seed and young seedlings. For maximum effectiveness, treat seed uniformly. Use the higher rate to provide increased length of protection and from heavy insect pressure and from wireworms, and to reduce potential spread of Barley yellow dwarf virus due to aphid vectors.

## POTATO:

To aid in control of insects including aphids, Colorado potato beetle, flea beetle, potato leafhopper, and psyllids apply at 11.11 to 22.22 grams of product per 100 kg (0.18 oz to 0.35 oz/100 lb of seed) of cut seed-pieces. To reduce damage to seed pieces caused by wireworms (*Limonius* sp., and *Melanotus* sp.) apply 22.22 grams of Sepresto 75 WS per 100 kg of cut seed-pieces. Apply using a seed dust metering applicator so that cut seed-pieces are thoroughly covered with the mixture. Thoroughly clean and sanitize cutting machines, knives, trays, tables, barrels, equipment, trucks, and planters before cutting and planting seed pieces. Plant seed-pieces as soon as possible after cutting and treating in accordance with the recommendations of your local extension potato specialist.

## ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted



immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

## **LABELING OF TREATED SEED**

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.



## IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

### NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

### NET CONTENTS:

Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS (PENDING) 04/29/10



## Sub Label: For Water Soluble Package

# Sepresto 75 WS

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable for the control of listed insect pests.

#### ACTIVE INGREDIENTS:

Clothianidin.....56.25%  
Imidacloprid.....18.75%

OTHER INGREDIENTS: .....25.00%

TOTAL .....100.00%

E.P.A. Reg. No. 264-1081

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

For MEDICAL And TRANSPORTATION Emergencies ONLY Call 24 Hours A Day 1-800-334-7577  
For PRODUCT USE Information Call 1-866-99BAYER (1-866-992-2937)

### FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor for treatment advice.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>NOTE TO PHYSICIAN:</b> No specific antidote is available. Treat the patient symptomatically.	

### PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read entire label before using this product.**

For use in commercial seed treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All seeds treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## MIXING PROCEDURES

Apply Sepresto 75 WS water soluble bag as a water-based slurry utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease control. Thoroughly mix the recommended amount of Sepresto 75 WS into the required amount of water prior to adding flowable or liquid solution to the treater.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Nonrefillable container. Do not reuse or refill this container.

### OUTER PACKAGING

Outer packaging of this product is secondary packaging to contain water soluble plastic bags. Thoroughly rinse any soluble powder residue into application equipment; then offer for recycling if available or dispose of in a sanitary landfill.

### WATER SOLUBLE BAGS

Allow sufficient time for bags to dissolve before use. There is no container disposal once the bags have dissolved.

## FOR EARLY SEASON PROTECTION AGAINST LISTED INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

Each water soluble bag contains 4 oz (0.25 lb) of Sepresto 75 WS.



## LEAFY GREEN VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Lettuce (head)	Leafminer (suppression) Aphids	One bag to treat 80,000 seeds (Equivalent to 1.42 grams of Sepresto 75 WS per 1,000 seed which contains 0.798 g ai clothianidin and 0.266 g ai of imidacloprid per 1,000 seed)	One bag to treat 80,000 seeds (Equivalent to 0.05 ounces of Sepresto 75 WS per 1,000 seed which contains 0.028 oz ai clothianidin and 0.0094 oz ai of imidacloprid per 1,000 seed)
Lettuce (leaf)		One bag to treat 100,000 seeds (Equivalent to 1.14 grams of Sepresto 75 WS per 1,000 seed which contains 0.64 g ai clothianidin and 0.214 g ai of imidacloprid per 1,000 seed)	One bag to treat 100,000 seeds (Equivalent to 0.04 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0225 oz ai clothianidin and 0.0075 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## BRASSICA (COLE) LEAFY VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Cabbage	Aphids Flea beetle	One bag to treat 54,000 seeds (Equivalent to 2.12 grams of Sepresto 75 WS per 1,000 seed which contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	One bag to treat 54,000 seeds (Equivalent to 0.074 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

## LABELING OF TREATED SEED

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.



- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
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- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

#### **WATER SOLUBLE BAG RESTRICTIONS**

- Do not sell individual water soluble bags.
- Do not handle inner package with wet hands or wet gloves.
- Do not allow packages to become wet prior to application.
- Handle outer container carefully to prevent breakage of inner water soluble bags.
- Always reseal outer container in a manner that protects remaining bags from moisture.
- Do not remove the water soluble bags from the container except for immediate use.
- Use the entire contents of a water soluble bag, do not break open to use partial contents of water soluble bags.



## IMPORTANT: READ BEFORE USE

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**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

### NOTICE TO BUYER

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### NET CONTENTS:

Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS Sub (PENDING) 04/29/10



amended Sepresto 75 WS label with carrot/carrot rust fly use

Jamin Huang

to:

Kable Davis

04/29/2010 01:56 PM

Cc:

Venus Eagle

Show Details

Bo, Good afternoon.

Thank you very much for your checking and clarification. I know it is an extra work for you to do it. We appreciate your tireless effort and hard work. Attached please find an amended label with carrot/carrot rust fly. It is also in compliance with the 4/28/10 Notice of Registration. Thank you for stamping this amended label.

We are disappointed with the decision from the Agency's upper management to request us to delete the cucurbit vegetables and the fruiting vegetables, despite the fact that the Agency has the following two residue reports conducted at the proposed US use rates and the data showed low risk to pollinators. If you have the EFED review of these two reports, we would appreciate to have a copy. Thank you again for all of your extra work to get Sepresto 75 WS approved. It was not easy at all.

47961201 Bocksch, S. (2010) Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Sweet Pepper following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361762/01/1, S08/01368, M/361762/01/2/OCR. Unpublished study prepared by Eurofins - GAB GmbH. 130 p.

Submitter: BAYER CROPSCIENCE LP

Submitter No. Submission Date Accession No.

000264

01/28/10

479612 01

Administrative No: 000264-1081

47961202 Bocksch, S. (2010) Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Melon following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361798/01/1, S08/01369, M/361798/01/2/OCR. Unpublished study prepared by Eurofins - GAB GmbH. 196 p.

Submitter: BAYER CROPSCIENCE LP

Submitter No. Submission Date Accession No.

000264

01/28/10

479612 02



Administrative No: 000264-1081

Best Regards,  
Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

Davis.Kable@epamail.epa.gov

To Jamin Huang &lt;jamin.huang@bayercropscience.com&gt;

04/29/2010 09:21 AM

CC Eagle.Venus@epamail.epa.gov

Subject Re: Question - Re: Agency Letters and Stamped Labels (EPA Reg. No. 264-1081, 264-827, 264-755)

Jamin-

Thanks for the email. I asked for the deletion of the entire ROOT VEGETABLES section because there wasn't any supporting efficacy data for radish. In addition, the efficacy data did not support four out of the five pests for carrot. I missed that the efficacy data did support one pest (carrot rust fly) for carrots. I was working off an older review which only allowed a reduced claim of "suppression" for this singular pest. I'm assuming this was changed in the final review.

The requirement to delete both CUCURBIT VEGETABLES and FRUITING VEGETABLES sections of the label came from upper management. This decision wasn't based on PMRA's efficacy review, but rather pollinator concerns arising from the combination of 2 neoticotinoid active ingredients.

If you want me to stamp a new label that includes carrot and carrot rust fly, please send me a revised label that makes all of the other required changes. If you have any other questions, please let me know.

Enjoy your Thursday.

Sincerely,  
Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)



1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415  
Fax: 703 305-6596  
Email: davis.kable@epa.gov

From: Jamin Huang <jamin.huang@bayercropscience.com>

To: Kable Davis/DC/USEPA/US@EPA

Date: 04/29/2010 01:30 AM

Subject: Question - Re: Agency Letters and Stamped Labels (EPA Reg. No. 264-1081, 264-827, 264-755)

Bo, Good morning,

I have a jet lag and cannot sleep. Based on PMRA efficacy review (attached), we are puzzled as to why the Agency asked us to delete carrot from root vegetables, squash (winter), squash (summer), melon and cucumber in cucurbit vegetables, and tomato and pepper in fruiting vegetables as listed in the Notice of Registration (attached). These crops all have VSAD supported claim. To be consistent with the Canadian label for Sepresto, these crops with VSAD supported claim should also be maintained in the US label. We would appreciate your re-consideration to maintain these crops on the US label based on VSAD supported claim. Thank you.

Best Regards,  
Jamin

\*\*\*\*\*  
Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com



Davis.Kable@epamail.  
epa.gov

04/28/2010 12:52 PM

Jamin Huang  
<jamin.huang@bayercropscience.com>

To

Laws.Meredith@epamail.epa.gov

cc

Subject  
Agency Letters and Stamped Labels (EPA  
Reg. No. 264-1081, 264-827, 264-755)

Jamin-

I hope you are having a great Wednesday. The attachment below includes the registration notice for Sepestro (EPA Reg. No. 264-1081), the acceptance letters for EPA Reg. No. 264-827 and 264-755, and the first page of the stamped label for each. I tried to scan the entire documents, however they were too large to email. I will also mail you paper copies of everything, including copies of the reviews. If you have any questions, please give me a call.

Enjoy the rest of your work week.

Sincerely,  
Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415

Fax: 703 305-6596

Email: davis.kable@epa.gov

----- Forwarded by Kable Davis/DC/USEPA/US on 04/28/2010 12:46 PM -----

From: cts/cts/QP/USEPA/US

To: Kable Davis/DC/USEPA/US@EPA

Date: 04/28/2010 12:42 PM



Subject:

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. (See attached file: [Untitled].pdf) [attachment "[Untitled].pdf" deleted by Jamin Huang/MOAJ/US/BCS/BAYER]

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

For alternate languages please go to <http://bayerdisclaimer.bayerweb.com> (See attached file: PMRA Efficacy Review of Sepresto.doc) (See attached file: 2010-04-28 NOR of Sepresto 75 WS 264-1081.pdf)

[attachment "PMRA Efficacy Review of Sepresto.doc" deleted by Jamin Huang/MOAJ/US/BCS/BAYER] [attachment "2010-04-28 NOR of Sepresto 75 WS 264-1081.pdf" deleted by Jamin Huang/MOAJ/US/BCS/BAYER]



# Material to be added to an e-Jacket/Jacket

Reg. No. 264-1081

Decision # 399489

Description:

new registration

1. Placement within the e-Jacket/jacket:

☐ Default: (chronological, top = newest)

☐ File Location: (eg. "before page 45 in .pdf")

2. ☒ Send to Data Extraction contractors this material:

☒ Newly stamped accepted label

☐ Notification

☒ New CSF

☐ Other: \_\_\_\_\_

3. Attach this coversheet to the top of the material or jacket. It must be well organized and clipped together, NOT STAPLED. Then give the material with this coversheet to staff in the Information Services Center (Room S-4900).

Reviewer:

XLB

Division: RD

Phone:

306-0415

Date:

4-28-10





U.S. ENVIRONMENTAL PROTECTION AGENCY  
Office of Pesticide Programs  
Registration Division (7505C)  
1200 Pennsylvania Ave., N.W.  
Washington, D.C. 20460

EPA Reg. Number:

264-1081

Date of Issuance:

APR 28 2010

NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration

(under FIFRA, as amended)

Term of Issuance:

Conditional

Name of Pesticide Product:

Sepresto 75 WS

Name and Address of Registrant (include ZIP Code):

Bayer CropScience  
2 T.W. Alexander Dr.  
Raleigh, NC 27709

**Note:** Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Registration Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA section 3(c)(7)(A) provided that you:

1. Submit and/or cite all data required for registration/reregistration/registration review of your product when the Agency requires all registrants of similar products to submit such data.
2. Make the following label changes before you release the product for shipment:
  - a. Revise the EPA Registration Number to read, "EPA Reg. No. 264-1081".
  - b. Due to lack of efficacy for radish and carrot, per the conclusions of EPA's joint review with Canada's Pesticide Management Regulatory Authority (PMRA), delete the **ROOT VEGETABLES** section of label (page 2).

Signature of Approving Official:

Meredith F. Laws, Branch Chief  
Insecticide-Rodenticide Branch, Registration Division (7505P)

Date:

APR 28 2010



- c. Due to lack of efficacy for spinach, per the conclusions of EPA's joint review with Canada's Pesticide Management Regulatory Authority (PMRA), delete the **LEAFY GREEN VEGETABLES** section of the label (page 3).
- d. Due to lack of efficacy, per the conclusions of EPA's joint review with Canada's Pesticide Management Regulatory Authority (PMRA), delete "*Mustard green*" from the **BRASSICA (COLE) LEAFY VEGETABLES** section of the label (page 5).
- e. The following sections must be deleted from the label:
  - **CUCURBIT VEGETABLES** (page 4)
  - **FRUITING VEGETABLES** (page 4)
- f. Within the broccoli portion of the **BRASSICA (COLE) LEAFY VEGETABLES** section of the label (page 5), delete the pests "*imported cabbageworm*" and "*cabbage maggot*."
- g. On pages 2 and 9, revise the statement "**FOR EARLY SEASON PROTECTION AGAINST CERTAIN INSECTS**" to read "**FOR EARLY SEASON PROTECTION AGAINST LISTED INSECTS**".
- h. Within the cabbage portion of the **BRASSICA (COLE) LEAFY VEGETABLES** section of the WSB sub-label (page 10), delete the pests "*imported cabbageworm*" and "*cabbage maggot*."
- i. Immediately above the statement "*Do not sell individual water soluble bags.*", located on page 10, include the header "**WATER SOLUBLE BAG RESTRICTIONS**".
- j. Within the ingredient statements, located on pages 1 and 8, revise "100.0%" to read "100.00%".
- k. Within the **STORAGE AND DISPOSAL** section of the WSB sub-label (page 9), revise the container disposal language to read as follows:

**CONTAINER DISPOSAL**

Nonrefillable container. Do not reuse or refill this container.

**OUTER PACKAGING**

Outer packaging of this product is secondary packaging to contain water soluble plastic bags. Thoroughly rinse any soluble powder residue into application equipment; then offer for recycling if available or dispose of in a sanitary landfill.

**WATER SOLUBLE BAGS**

Allow sufficient time for bags to dissolve before use. There is no container disposal once the bags have dissolved.

- 3. Per the Agency's clothianidin risk assessment (D357034), data are required demonstrating the stability of the TZNG method in frozen soybean commodities for up to 18 months. These data



are a condition of registration and must be submitted to the Agency within 24 months of the date of this notice.

4. Per the Agency's imidacloprid risk assessment (D375406), a guideline (870.7800) Immunotoxicity study must be submitted. Within one month of the date of this notice, Bayer CropScience must submit to the Agency a suggested timeline of when the data will be conducted and then submitted for review. These data are a condition of registration.
5. The data requirements for storage stability (830-6317) and corrosion characteristics (830-6320) have not been satisfied, and must be submitted within eighteen months of the date of this letter.
6. Should you wish to retain a reference to the company's website on your label, the website then becomes labeling under the Federal Insecticide Fungicide and Rodenticide Act and is subject to review by the Agency. If the website is false or misleading, the product would be misbranded and unlawful to sell or distribute under FIFRA section 12(a)(1)(E). 40 CFR 156.10(a)(5) list examples of statements EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore should the Agency find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.
7. Submit one copy of the revised final printed label for the record before you release the product for shipment.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA section 6(e). Your release for shipment of the product constitutes acceptance of these conditions.

A stamped copy of the label is enclosed for your records. If you have any questions regarding this notice, please contact Kable Bo Davis at (703) 306-0415 or [davis.kable@epa.gov](mailto:davis.kable@epa.gov).

Meredith F. Laws  
Branch Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505P)



APR 28 2010

Under the Federal Insecticide,  
Fungicide, and Rodenticide Act,  
as amended, for the pesticide  
registered under EPA Reg. No.  
264-1081

# Sepresto 75 WS

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable and cereal seed, or as a potato seed piece treatment for the control of listed insect pests.

## ACTIVE INGREDIENTS:

Clothianidin.....56.25%  
Imidacloprid.....18.75%

OTHER INGREDIENTS: .....25.00%

TOTAL .....100.0%

E.P.A. Reg. No. 264-XXXX

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.  
(If you do not understand the label, find someone to explain it to you in detail.)

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577

For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

## FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor for treatment advice.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>NOTE TO PHYSICIAN:</b> No specific antidote is available. Treat the patient symptomatically.	

## PRECAUTIONARY STATEMENTS

### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read entire label before using this product.**

For use in commercial seed treaters only, with the exception of application to cereal grain crops (Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat), which may be made either by commercial seed treatment or as an end-use seed treatment on agricultural establishments immediately before planting, and with the exception of application to potato, which may be made on agricultural establishments using a seed dust metering applicator to seed-pieces immediately before planting. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All vegetable and cereal grain seed treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available or dispose of in a sanitary landfill or by incineration, or if allowed by state and local authorities, by burning. If burned, stay out of smoke.

## FOR EARLY SEASON PROTECTION AGAINST CERTAIN INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

## ROOT VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Radish	Cabbage maggot	0.8 (contains 0.45 g ai clothianidin and 0.15 g ai imidacloprid per 1,000 seed)	0.028 (contains 0.01575 oz ai clothianidin and 0.00525 oz ai imidacloprid per 1,000 seed)
Carrot	Whitefly White grub Cutworm, black Weevil Carrot rust fly	0.12 to 0.21 (contains 0.0675 to 0.118 g ai clothianidin and 0.0225 to 0.0394 g ai of imidacloprid per 1,000 seed)	0.0042 to 0.0074 (contains 0.0024 to 0.0042 oz ai clothianidin and 0.00079 to 0.0014 oz ai imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.



**BULB VEGETABLES**

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1000 seed	Ounces of Sepresto 75 WS per 1000 seed
Onion (bulb)	Onion maggot	0.21 to 0.32	0.0074 to 0.011
	Seedcorn maggot	(contains 0.118 to 0.18 g ai clothianidin and 0.039 to 0.06 g ai of imidacloprid per 1,000 seed)	(contains 0.0042 to 0.006 oz ai clothianidin and 0.0014 to 0.0020 oz ai of imidacloprid per 1000 seed)
	Thrips		
Leek	Onion maggot	0.36	0.0126
	Seedcorn maggot	(contains 0.20 g ai clothianidin and 0.0675 g ai of imidacloprid per 1,000 seed)	(contains 0.0071 oz ai clothianidin and 0.0024 oz ai of imidacloprid per 1,000 seed)
	Thrips		
Onion (bunching)		0.160 to 0.188	0.0056 to 0.0065
		(contains 0.09 to 0.106 g ai clothianidin and 0.03 to 0.035 g ai of imidacloprid per 1,000 seed)	(contains 0.0032 to 0.0037 oz ai clothianidin and 0.001 to 0.0012 oz ai of imidacloprid per 1,000 seed)

**Restrictions**

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

**LEAFY GREEN VEGETABLES**

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Spinach	Leafminer	0.28	0.0098
	(suppression)	(contains 0.157 g ai clothianidin and 0.052 g ai of imidacloprid per 1,000 seed)	(contains 0.00551 oz ai clothianidin and 0.00184 oz ai of imidacloprid per 1,000 seed)
	Aphids		

**Restrictions**

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.



## CUCURBIT VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup> Grams of Sepresto 75 WS per 1,000 seed	Rate <sup>1</sup> Ounces of Sepresto 75 WS per 1,000 seed
Squash (Winter)	Aphids	1.77	0.062
Squash (summer)	Thrips	(contains 0.995 g ai clothianidin and 0.33 g ai imidacloprid per 1,000 seed)	(contains 0.034 oz ai clothianidin and 0.011 oz ai of imidacloprid per 1,000 seed)
Melon	Seedcorn maggot		
Cucumber	Cucumber beetle		
<b>Restrictions</b>			
<sup>1</sup> Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz clothianidin and 8 oz imidacloprid per acre per cropping cycle.			

## FRUITING VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup> Grams of Sepresto 75 WS per 1,000 seed	Rate <sup>1</sup> Ounces of Sepresto 75 WS per 1,000 seed
Tomato	Aphids	0.067 to 0.177	0.0023 to 0.0062
	Flea beetle	(contains 0.0377 to 0.099 g ai clothianidin and 0.0125 to 0.033 g ai of imidacloprid per 1,000 seed)	(contains 0.00129 to 0.00348 oz ai clothianidin and 0.00043 to 0.00116 oz ai of imidacloprid per 1,000 seed)
	Leafminer (suppression)		
	Tomato beet armyworm		
	Thrips		
	Whitefly		
Pepper	Aphids	0.88	0.031
	Flea beetle	(contains 0.495 g ai clothianidin and 0.165 g ai of imidacloprid per 1,000 seed)	(contains 0.0174 oz ai clothianidin and 0.00581 oz ai of imidacloprid per 1,000 seed)
	Leafminer		
	Thrips		
	Whitefly		
<b>Restrictions</b>			
<sup>1</sup> Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz clothianidin and 8 oz imidacloprid per acre per cropping cycle.			



## BRASSICA (COLE) LEAFY VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
		Grams of Sepresto 75 WS per 1,000 seed	Ounces of Sepresto 75 WS per 1,000 seed
Broccoli	Aphids	2.12	0.074
	Imported cabbageworm	(contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	(contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)
	Cabbage maggot		
	Flea beetle		
Mustard green	Flea beetle	0.177	0.0062
		(contains 0.0995 g ai clothianidin and 0.03318 g ai of imidacloprid per 1,000 seed)	(contains 0.00348 oz ai clothianidin and 0.001162 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.

## CROPS OF CEREAL GRAINS EXCEPT RICE:

**Crops of Crop Group 15 except Rice including:** Barley, Buckwheat, Corn, Millet (pearl and proso), Oats, Popcorn, Rye, Sorghum, Teosinte, Triticale, Wheat

To provide early season protection of seedlings against injury by aphids (including Bird cherry-oat, English grain, Greenbug, and Russian wheat aphid), Hessian fly, apply at 41.3 g to 124 g of formulated product per 100 kg of seed (0.66 oz to 2.0 oz/100 lb of seed) prior to planting as a slurry treatment. Low use rate for "wireworm-only" protection: Sepresto 75 WS applied at 6.7 – 13.3 g per 100 kg seed (0.11 oz to 0.21 oz/100 lb of seed) offers suppression of wireworm activity on seed and young seedlings. For maximum effectiveness, treat seed uniformly. Use the higher rate to provide increased length of protection and from heavy insect pressure and from wireworms, and to reduce potential spread of Barley yellow dwarf virus due to aphid vectors.

## POTATO:

To aid in control of insects including aphids, Colorado potato beetle, flea beetle, potato leafhopper, and psyllids apply at 11.11 to 22.22 grams of product per 100 kg (0.18 oz to 0.35 oz/100 lb of seed) of cut seed-pieces. To reduce damage to seed pieces caused by wireworms (*Limoniussp.*, and *Melanotus sp.*) apply 22.22 grams of Sepresto 75 WS per 100 kg of cut seed-pieces. Apply using a seed dust metering applicator so that cut seed-pieces are thoroughly covered with the mixture. Thoroughly clean and sanitize cutting machines, knives, trays, tables, barrels, equipment, trucks, and planters before cutting and planting seed pieces. Plant seed-pieces as soon as possible after cutting and treating in accordance with the recommendations of your local extension potato specialist.

## ROTATIONAL CROPS:

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

## LABELING OF TREATED SEED

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.



- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.



## IMPORTANT: READ BEFORE USE

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

**DISCLAIMER OF WARRANTIES:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE MAKES NO OTHER WARRANTIES, EXPRESS OR IMPLIED, OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE OR OTHERWISE, THAT EXTEND BEYOND THE STATEMENTS MADE ON THIS LABEL. No agent of Bayer CropScience is authorized to make any warranties beyond those contained herein or to modify the warranties contained herein. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, BAYER CROPSCIENCE DISCLAIMS ANY LIABILITY WHATSOEVER FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT.

**LIMITATIONS OF LIABILITY:** TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER FOR ANY AND ALL LOSSES, INJURIES OR DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE, SHALL NOT EXCEED THE PURCHASE PRICE PAID, OR AT BAYER CROPSCIENCE'S ELECTION, THE REPLACEMENT OF PRODUCT.

### NOTICE TO BUYER

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

### NET CONTENTS:

Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS (PENDING) 08/01/08, Resubmitted 03/26/10, Resubmitted 03/29/10, Resubmitted 03/31/10



## Sub Label: For Water Soluble Package

# Sepresto 75 WS

Sepresto 75 WS is a systemic insecticide seed treatment for use on listed vegetable for the control of listed insect pests.

#### ACTIVE INGREDIENTS:

Clothianidin.....56.25%  
Imidacloprid.....18.75%

OTHER INGREDIENTS: .....25.00%

TOTAL .....100.0%

E.P.A. Reg. No. 264-XXXX

E.P.A. Est. No.

## KEEP OUT OF REACH OF CHILDREN CAUTION

Si usted no entiende la etiqueta, busque a alguien para que se la explique a usted en detalle.

(If you do not understand the label, find someone to explain it to you in detail.)

For **MEDICAL** And **TRANSPORTATION** Emergencies **ONLY** Call 24 Hours A Day 1-800-334-7577

For **PRODUCT USE** Information Call 1-866-99BAYER (1-866-992-2937)

### FIRST AID

IF ON SKIN OR CLOTHING:	<ul style="list-style-type: none"><li>• Take off contaminated clothing.</li><li>• Rinse skin immediately with plenty of water for 15-20 minutes.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
IF SWALLOWED:	<ul style="list-style-type: none"><li>• Immediately call a poison control center or doctor for treatment advice.</li><li>• Do not induce vomiting unless told to do so by a poison control center or doctor.</li><li>• Have person sip a glass of water if able to swallow.</li><li>• Do not give anything by mouth to an unconscious person.</li></ul>
IF IN EYES:	<ul style="list-style-type: none"><li>• Hold eye open and rinse slowly and gently with water for 15-20 minutes.</li><li>• Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.</li><li>• Call a poison control center or doctor for treatment advice.</li></ul>
For <b>MEDICAL</b> Emergencies Call 24 Hours A Day 1-800-334-7577.	
Have the product container or label with you when calling a poison control center or doctor or going for treatment.	
<b>NOTE TO PHYSICIAN:</b> No specific antidote is available. Treat the patient symptomatically.	

### PRECAUTIONARY STATEMENTS

#### HAZARD TO HUMANS AND DOMESTIC ANIMALS

#### CAUTION

Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing.

#### PERSONAL PROTECTIVE EQUIPMENT (PPE)

Some materials that are chemical-resistant to this product are listed below. If you want more options, follow the instructions for category C on an EPA chemical resistance category selection chart.

**Applicators and other handlers must wear:** Long-sleeved shirt and long pants, chemical-resistant gloves (such as nitrile, butyl, neoprene, barrier laminate, polyvinyl chloride or Viton) and shoes plus socks. Treaters must also wear a dust/filtering respirator (MSHA/NIOSH approval number prefix TC-21C) when mixing and loading the formulation.

Follow manufacturer's instructions for cleaning/maintaining PPE. If no instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.



## USER SAFETY RECOMMENDATIONS

**Users should:** Wash hands thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

## ENVIRONMENTAL HAZARDS

This pesticide is highly toxic to birds and aquatic invertebrates. For terrestrial uses, do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters. Cover or incorporate spilled treated seeds.

## DIRECTIONS FOR USE

**It is a violation of Federal law to use this product in a manner inconsistent with its labeling.  
Read entire label before using this product.**

For use in commercial seed treaters only. Not for use in agricultural establishments in hopper-box, slurry-box, or similar on farm seed treatment applicators used at planting.

All seeds treated with this product must be conspicuously colored at the time of treatment. This product contains no colorant. An appropriate colorant must be added when this product is applied to seed to distinguish and prevent subsequent inadvertent use as a food for man or feed for animals. Regulations pertaining to coloration of treated seed enforced by 40 CFR 153.155 must be strictly adhered to when using this product.

## MIXING PROCEDURES

Apply Sepresto 75 WS water soluble bag as a water-based slurry utilizing standard slurry seed treatment equipment which provides uniform seed coverage. Uneven or incomplete seed coverage may not give the desired level of disease control. Thoroughly mix the recommended amount of Sepresto 75 WS into the required amount of water prior to adding flowable or liquid solution to the treater.

## STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

### PESTICIDE STORAGE

Store in a cool, dry secured storage area.

### PESTICIDE DISPOSAL

Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility.

### CONTAINER DISPOSAL

Non-refillable container. Do not reuse or refill this container. Offer for recycling if available.

## FOR EARLY SEASON PROTECTION AGAINST CERTAIN INSECTS:

Sepresto 75 WS will aid in the protection of seeds and seedlings against injury by certain early season insects. Bayer CropScience makes no claims as to the effect of this product on germination of seed. All such risks shall be assumed by the user or buyer.

Pre-test the germination of a small sample of each seed lot to be treated with Sepresto 75 WS prior to commercial application to the whole lot. Re-test carry-over seed treated with Sepresto 75 WS before releasing seed to commercial dealers and distributors for sale.

Each water soluble bag contains 4 oz (0.25 lb) of Sepresto 75 WS.

## LEAFY GREEN VEGETABLES

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Lettuce (head)	Leafminer (suppression)  Aphids	One bag to treat 80,000 seeds (Equivalent to 1.42 grams of Sepresto 75 WS per 1,000 seed which contains 0.798 g ai clothianidin and 0.266 g ai of imidacloprid per 1,000 seed)	One bag to treat 80,000 seeds (Equivalent to 0.05 ounces of Sepresto 75 WS per 1,000 seed which contains 0.028 oz ai clothianidin and 0.0094 oz ai of imidacloprid per 1,000 seed)
Lettuce (leaf)		One bag to treat 100,000 seeds (Equivalent to 1.14 grams of Sepresto 75 WS per 1,000 seed which contains 0.64 g ai clothianidin and 0.214 g ai of imidacloprid per 1,000 seed)	One bag to treat 100,000 seeds (Equivalent to 0.04 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0225 oz ai clothianidin and 0.0075 oz ai of imidacloprid per 1,000 seed)

### Restrictions

<sup>1</sup>Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.



**BRASSICA (COLE) LEAFY VEGETABLES**

Crop	Pests Controlled	Rate <sup>1</sup>	Rate <sup>1</sup>
Cabbage	Aphids Imported cabbageworm Cabbage maggot Flea beetle	One bag to treat 54,000 seeds (Equivalent to 2.12 grams of Sepresto 75 WS per 1,000 seed which contains 1.1925 g ai clothianidin and 0.3975 g ai of imidacloprid per 1,000 seed)	One bag to treat 54,000 seeds (Equivalent to 0.074 ounces of Sepresto 75 WS per 1,000 seed which contains 0.0416 oz ai clothianidin and 0.01387 oz ai of imidacloprid per 1,000 seed)
<b>Restrictions</b> <sup>1</sup> Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin and 8 oz ai imidacloprid per acre per cropping cycle.			

**ROTATIONAL CROPS:**

Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.

**LABELING OF TREATED SEED**

The Federal Seed Act requires that the container of seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the US Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75 WS:

- Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz ai clothianidin or 8 oz ai imidacloprid per acre per cropping cycle.
- Store away from feeds and foodstuffs.
- Wear long-sleeved shirt, long pants, shoes, socks, and chemical-resistant gloves when handling treated seed.
- Dispose of all excess treated seed. Left over treated seed may be double sown around the headland or buried away from water sources in accordance with local requirements. Do not contaminate water bodies when disposing of planting equipment washwaters.
- Dispose of seed packaging in accordance with local requirements.
- This compound is toxic to birds and mammals. Treated seeds exposed on soil surface may be hazardous to birds and mammals. Cover or collect treated seeds spilled during loading.
- Treated areas may be replanted with any crop specified on both imidacloprid and clothianidin labels, or any crop for which a tolerance exists for both active ingredients, as soon as practical following the last application. Areas planted with treated seed may be replanted immediately with cotton, corn, rapeseed, sorghum, sugar beet, potato, cereal grains (Crop Group 15 except rice), canola, and the following vegetable crops: root vegetables (Crop Group 1), bulb vegetables (Crop Group 3), leafy green vegetables (Crop Group 4A), Brassica (cole) leafy vegetables (Crop Group 5), fruiting vegetables (Crop Group 8), cucurbit vegetables (Crop Group 9). These areas may also be replanted after 30 days with soybeans, dried beans and dried peas. Do not plant any other crop in the treated area for at least one year after treated seeds are planted.
- Do not sell individual water soluble bags.
- Do not handle inner package with wet hands or wet gloves.
- Do not allow packages to become wet prior to application.
- Handle outer container carefully to prevent breakage of inner water soluble bags.



- Always reseal outer container in a manner that protects remaining bags from moisture.
- Do not remove the water soluble bags from the container except for immediate use.
- Use the entire contents of a water soluble bag, do not break open to use partial contents of water soluble bags.

### **IMPORTANT: READ BEFORE USE**

Read the entire Directions for Use, Conditions, Disclaimer of Warranties and Limitations of Liability before using this product. If terms are not acceptable, return the unopened product container at once.

By using this product, user or buyer accepts the following Conditions, disclaimer of Warranties and Limitations of Liability.

Treatment of highly mechanically damaged seed, or seed of known low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small portion of seed before committing the total seed lot to a selected chemical treatment. Due to seed quality conditions beyond the control of Bayer CropScience LP, no claims are made to guarantee germination of carry-over seed.

**CONDITIONS:** The directions for use of this product are believed to be adequate and must be followed carefully. However, it is impossible to eliminate all risks associated with the use of this product. Crop injury, ineffectiveness or other unintended consequences may result because of such factors as weather conditions, presence of other materials, or the manner of use or application, all of which are beyond the control of Bayer CropScience. All such risks shall be assumed by the user or buyer.

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#### **NOTICE TO BUYER**

Purchase of this material does not confer any rights under patents governing this product or the use thereof in countries outside of the United States.

#### **NET CONTENTS:**

Produced for



**Bayer CropScience**

Bayer CropScience LP  
P.O. Box 12014, 2 T.W. Alexander Drive  
Research Triangle Park, North Carolina 27709  
1-866-99BAYER (1-866-992-2937)  
<http://www.bayercropscienceus.com>

Sepresto 75 WS Sub (PENDING) 08/01/08, Resubmitted 03/26/10, Resubmitted 03/29/10, Resubmitted 03/31/10, Resubmitted 04/01/10



revised Sepresto 75WS label (for non-WSP and for WSP) - 2010-04-01 version

Jamin Huang

to:

Kable Davis

04/01/2010 10:54 AM

Cc:

Meshea Brodie

Show Details

resubmission

4-1-10

revised label

Bo,

Attached please find a copy of amended label for Sepresto 75WS based on your yesterday's e-mail. As usual, one copy is clean version and the other has changes highlighted in yellow. Please let me know if you have any questions.

Have a great afternoon,

Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634

e-mail: jamin.huang@bayercropscience.com

Davis.Kable@epamail.epa.gov

To Jamin Huang <jamin.huang@bayercropscience.com>

cc

03/31/2010 05:22 PM

Subject Re: revised Sepresto 75WS label (for non-WSP and for WSP)

Jamin-

I just called and left a message. I was hoping to catch you before you left. The following changes are required within the WSB sub-label.

1. The sub-label must indicate how much product is contained within each WSB. Please include the amount of total product and the amount of each active ingredient.
2. The directions for use within the sub-label must be revised to indicate how many bags are required for each crop. In addition, the directions for use must include instructions how to apply the bags (i.e., how to mix with water....).
3. The sub-label must include the following additional restrictions:



## Restrictions for water soluble bags:

- Do not sell individual water soluble bags.
- Do not handle inner package with wet hands or gloves.
- Do not allow packages to become wet prior to application.
- Handle outer container carefully to prevent breakage of inner water soluble bags.
- Always reseal outer container in a manner that protects remaining bags from moisture.
- Do not remove the water soluble bags from the container except for immediate use.
- Use the entire contents of a water soluble bag, do not break open to use partial contents of water soluble bags.

If you have any questions, please give me a call. Thanks for working so hard on this, Jamin.

Sincerely,  
Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415  
Fax: 703 305-6596  
Email: davis.kable@epa.gov

From: Jamin Huang <jamin.huang@bayercropscience.com>

To: Kable Davis/DC/USEPA/US@EPA

Cc: Meshea Brodie <meshea.brodie@bayercropscience.com>

Date: 03/31/2010 04:39 PM

Subject: revised Sepresto 75WS label (for non-WSP and for WSP)



Bo,

Attached please find a combination of 1) the label for Sepresto 75WS with all of the crops except for the ones requiring WSP and 2) the sub-label for WSP with 3 crops [lettuce (head, leaf) and cabbage] Both have the same EPA Reg No.. The labeling language is similar/identical for both labels, except for use directions and container disposal language. All of the requested changes from you in the past several days are incorporated. Please let me know if you have any questions. The sub-label (pages 8 to 11) is right behind the label (pages 1 to 7).

Best Regards,  
Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

Davis.Kable@epamail.epa.gov  
v

03/31/2010 03:25 PM

To  
Jamin Huang  
<jamin.huang@bayercropscience.com>

cc

Subject  
Additional Changes

Jamin-

Thanks for the phone discussion earlier. Please see below for one additional required change:

1. Within the LABELING OF TREATED SEED section of the label, revise the sentence "Wear long-sleeved shirt, long pants and waterproof gloves when



handling treated seed." to read "Wear long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves when handling treated seed."

Please email me a revised label which contains all the changes we have discussed within the last couple of days. If you have any questions, please give me a call.

Thanks-  
Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415  
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[attachment "P Combo Sepresto 75WS & Sub 08-01-08, 03-26-10, 03-29, 03-31-10 shaded.pdf" deleted by Kable Davis/DC/USEPA/US] [attachment "P Combo Sepresto 75WS & Sub 08-01-08, 03-26-10, 03-29, 03-31-10.pdf" deleted by Kable Davis/DC/USEPA/US]



revised Sepresto 75WS label (for non-WSP and for WSP)

Jamin Huang

to:

Kable Davis

03/31/2010 04:39 PM

Cc:

Meshea Brodie

Show Details

resubmission  
3-31-10  
revised label

History: This message has been replied to.

Bo,

Attached please find a combination of 1) the label for Sepresto 75WS with all of the crops except for the ones requiring WSP and 2) the sub-label for WSP with 3 crops [lettuce (head, leaf) and cabbage] Both have the same EPA Reg No.. The labeling language is similar/identical for both labels, except for use directions and container disposal language. All of the requested changes from you in the past several days are incorporated. Please let me know if you have any questions. The sub-label (pages 8 to 11) is right behind the label (pages 1 to 7).

Best Regards,

Jamin

\*\*\*\*\*  
Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634

e-mail: jamin.huang@bayercropscience.com

Davis.Kable@epamail.epa.gov

To Jamin Huang <jamin.huang@bayercropscience.com>

cc

03/31/2010 03:25 PM

Subject Additional Changes

Jamin-

Thanks for the phone discussion earlier. Please see below for one additional required change:

1. Within the LABELING OF TREATED SEED section of the label, revise the



sentence "Wear long-sleeved shirt, long pants and waterproof gloves when handling treated seed." to read "Wear long-sleeved shirt, long pants, shoes, socks and chemical-resistant gloves when handling treated seed."

Please email me a revised label which contains all the changes we have discussed within the last couple of days. If you have any questions, please give me a call.

Thanks-  
Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415  
Fax: 703 305-6596  
Email: davis.kable@epa.gov

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March 29, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

resubmission

alternate CSF

3-25-10

**ATTENTION:** Kable Bo Davis (Acting PM 07, RD, Insecticide-Rodenticide Branch)

**Re: Submission of Alternate CSF for Sepresto 75 WS  
(EPA File Symbol: 264-RNIR)**

Dear Mr. Davis,

Per your request, Bayer CropScience is herein submitting 3 copies of an alternate Confidential Statement of Formula (to be used as water soluble package) for Sepresto 75 WS.

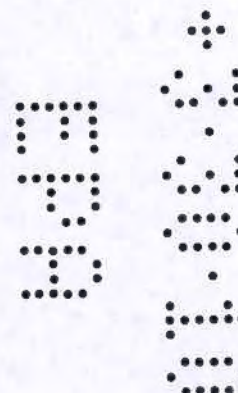
Please contact me at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding this submission.

Sincerely,

A handwritten signature in black ink, appearing to read "Jamin Huang". The signature is fluid and cursive.

Jamin Huang, Ph.D.  
Senior Regulatory Manager

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000





amended Sepresto 75WS label (v.2)  
Jamin Huang  
to:  
Kable Davis  
03/29/2010 01:27 PM  
Show Details

resubmission  
3-29-10  
revised label

Bo,

Attached please find an amended label for Sepresto 75WS (v.2). One is the clean copy. The other has all of revisions highlighted in yellow in relation to the pending 08/01/2008 label. This has additional revisions in the First Aid/Hazard to Humans and Domestic Animals/Personal Protective Equipment/User Safety Recommendations sections (to be in sync with the EPA/PMRA's review) and in the seed tag section (per your e-mail instruction). Please let me know if you have any questions.

Best Regards,  
Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com)

---

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Re: Additional Changes (EPA File Symbol 264-RNIR)

Jamin Huang

to:

Kable Davis

03/26/2010 10:11 AM

Show Details

resubmission

3-26-10

revised label

History: This message has been replied to.

Thank you for the e-mail, Bo, I am in an all-day long meeting today. I will work with a label specialist to do revision and send you an amended label. Best Regards, Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634

e-mail: jamin.huang@bayercropscience.com

Davis.Kable@epamail.epa.gov

To Jamin Huang <jamin.huang@bayercropscience.com>

cc

03/26/2010 10:05 AM

Subject Additional Changes (EPA File Symbol 264-RNIR)

Jamin-

I hope your Friday is going well. Please see below for additional changes to the label. These are in addition to the ones I gave you yesterday.

1. Please make changes per the attached acute toxicity review.
2. Revise the LABELING OF TREATED SEED section of the label to read as follows:

#### LABELING OF TREATED SEED

The Federal Seed Act requires that the container of corn seed treated with Sepresto 75 WS must be labeled with the following statements:

- This seed has been treated with Sepresto 75 WS, which contains imidacloprid and clothianidin.
- Do not use treated seed for food, feed or oil processing.

In addition, the U.S. Environmental Protection Agency requires the following statements on the container of seed treated with Sepresto 75



WS.

- Store away from feeds and foodstuffs.

\*\*\*\*\* Please include the remaining bullet points found on page 6 of the label.

If you have any questions, please give me a call. I left you a voice message earlier today discussing these changes.

Thanks!

Bo

Kable Bo Davis  
Acting Product Manager (07)  
U.S. Environmental Protection Agency  
Insecticide-Rodenticide Branch  
Registration Division (7505P)  
1200 Pennsylvania Ave. NW  
Washington, DC 20460

Tel: 703 306-0415

Fax: 703 305-6596

Email: davis.kable@epa.gov

----- Forwarded by Kable Davis/DC/USEPA/US on 03/26/2010 09:53 AM -----

From: cts/cts/QP/USEPA/US

To: Kable Davis/DC/USEPA/US@EPA

Date: 03/26/2010 09:46 AM

Subject:

Please open the attached document. This document was digitally sent to you using an HP Digital Sending device. (See attached file: [Untitled].pdf)

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Residue data in/on pollen and nectar - Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call  
 Jamin Huang  
 to:  
 Meredith Laws  
 09/07/2009 03:14 PM  
 Cc:  
 Kable Davis, Roy Lidstone, Venus Eagle  
 Show Details

resubmission  
 9-7-09

Good afternoon, Meredith,

We just received the residue data of imidacloprid and clothianidin and 2 relevant metabolites from each of these two active ingredients in whole flower, nectar and pollen from melon, and in whole flower from sweet pepper. The seeds were treated with Sepresto 75 WS at the proposed use rates in the US. The results, compiled in the attached short report below, show that the risk to bees from Sepresto treated melon and pepper seeds is very low.

We hope that the residue data included in this e-mail and the other information previously provided to you in the 8/6 and 8/18 e-mails below address all of the questions raised by you in the 7/23 conference call. Please let us know if you have any questions.

Best Regards,  
 Jamin

\*\*\*\*\*  
 Jamin Huang, Ph.D.  
 Registration Product Manager  
 Bayer CropScience

tel: 919-549-2634  
 e-mail: jamin.huang@bayercropscience.com

Jamin Huang/MOAJ/US/BCS/BAYER

08/18/2009 04:36 PM

To "Meredith Laws" <Laws.Meredith@epamail.epa.gov>  
 cc "Kable "Bo" Davis" <Davis.Kable@epamail.epa.gov>, Roy  
 Lidstone/CSLIR/CA/BCS/BAYER@BAYER-CANADA-NOTES  
 Subject Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call [Link](#)

Good afternoon, Meredith,

In response to your questions re. a comparison of the stand alone imidacloprid seed treatment products and the Sepresto product in the 3rd paragraph of your 8/4/09 e-mail, we have the following comments. Please let us know if you would like to have additional information or clarification. I will send you the cucurbit pollen residue data when available. Would you like us to visit you to go over the cucurbit pollen residue data and any efficacy questions you might have?

Imidacloprid is currently registered as a seed treatment (via Gaucho) on several vegetable crops including carrots (for domestic use) as well as cucurbits (squash, melons, cucumbers) and fruiting vegetable (tomato and pepper). The use of Gaucho 480 FS and Gaucho 75 ST FS on cucurbits and fruiting vegetables is only for export of the treated seed. A comparison of the data for the current imidacloprid (Gaucho) seed treatment uses and the proposed imidacloprid rates for the Sepresto use is given in the attached table.

An accurate assessment of the different formulations can only be made when both the use rates and the pests controlled are considered. Attached please also find the information of "number of seeds of different crops per Lb or Kg" and "planting rates for different crops in lb seed/acre (or # of seed per ha)" which was previously provided to Venus, Bo and Michael Doherty on 1/29/09 per their request. The "number of seeds per lb" info is used here to calculate "g imidacloprid per 1,000 seeds" in the spreadsheet.

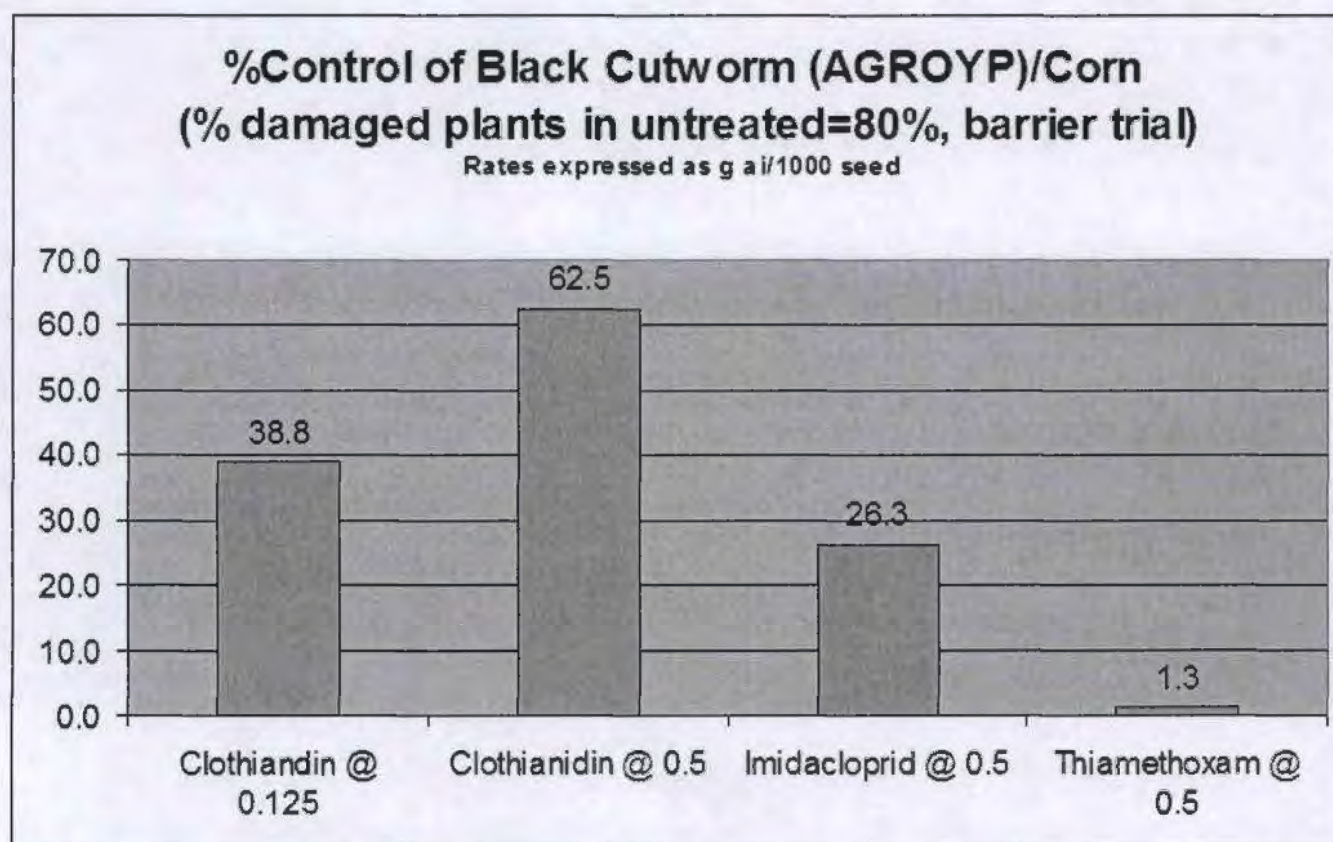
[attachment "Gaucho vs Sepresto - ST products and crop-pest-rate.xls" deleted by Jamin Huang/MOAJ/US/BCS/BAYER]  
 [attachment "Vegetable Rate Chart for Sepresto 75WS 1-21-2009.xls" deleted by Jamin Huang/MOAJ/US/BCS/BAYER]



For cucurbit vegetables the recommended imidacloprid use rates for squash, melons and cucumbers on the Gaucho labels are 3.0, 0.77 and 0.88 g ai/1,000 seed. The corresponding imidacloprid use rate for all cucurbits on the Sepresto label is 0.33 g ai/1,000 seed and the total CNI (imidacloprid + clothianidin) rate on the Sepresto label is 1.325 g ai/1,000 seed. Therefore, when considering the cucurbit crop group the imidacloprid rate and the total CNI rate on the Sepresto label are both less than the imidacloprid rate on the Gaucho labels. It should be noted that the Sepresto label contains two pests not included on the Gaucho labels (seed corn maggot and cucumber beetle.).

Similarly, looking at the fruiting vegetables crop group (tomatoes and peppers) the imidacloprid use rate on the Gaucho 75 ST FS ranges from 0.14 g ai/1,000 seed for tomato to 0.33 g ai/1,000 seed for peppers. The corresponding imidacloprid rates on the Sepresto label are 0.0125 to 0.033 g ai/1,000 seed for tomato and 0.165 g ai/1,000 seed for pepper. The total CNI rate for fruiting vegetables is 0.0502 to 0.132 g ai/1,000 seed for tomato and 0.66 g ai/1,000 seed for pepper. Therefore, the imidacloprid rate on the Sepresto label is less than the imidacloprid rate on the Gaucho label. In addition, the total CNI rate on the Sepresto label is less than the imidacloprid rate for tomatoes on the Gaucho label. Although the total CNI rate for peppers on the Sepresto label is 2X that of the imidacloprid rate on the Gaucho label, the Sepresto label contains significantly more pests not seen on the Gaucho labels.

For carrots, the imidacloprid rate and the total CNI rate on the Sepresto label are both higher than the imidacloprid rate on the Gaucho labels. However, the pests on the Sepresto label are significantly different than those on the Gaucho labels. The cutworm data below demonstrate that CNIs (such as, imidacloprid, clothianidin and thiamethoxam) are not all equal in their efficacy.



All rates and pests listed in the Sepresto label are the result of four or more years of trials testing seed treatment applications of clothianidin, imidacloprid, or clothianidin + imidacloprid. Since seed treatments are largely protective in application (i.e. the treated seed is planted before the pest appears), one would choose the chemical combination and rates to cover as many key pests as possible. This is different from foliar sprays that are applied whenever pests appear and growers can use different products depending on the pest spectrum.

Therefore, as the examples above indicate, use of Sepresto can actually result in a reduction in the seed treatment use rate of CNIs on some crops because of the specific pests controlled by each active ingredient. In addition, the seed treatment use of Sepresto can result in a reduction in the amount of CNI applied by foliar applications. Therefore, both imidacloprid and clothianidin are needed at the proposed rates in the Sepresto seed treatment formulation in order to control the pests given on the Sepresto label.



Best Regards,  
Jamin

\*\*\*\*\*  
Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

Jamin Huang/MOAJ/US/BCS/BAYER

08/06/2009 08:37 AM

To "Meredith Laws" <Laws.Meredith@epamail.epa.gov>  
cc "Kable "Bo" Davis" <Davis.Kable@epamail.epa.gov>, Roy  
Lidstone/CSLIR/CA/BCS/BAYER@BAYER-CANADA-NOTES  
Subject Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call [Link](#)

Good morning, Meredith,

Attached please find the requested Part 10 that has been reviewed by PMRA (248 pages). Some new efficacy data is also included below (7 pages). We will also compile a comparative table to respond to your questions in the 3rd paragraph early next week. Please let us know if you have any questions.

Best Regards,  
Jamin

[attachment "Sepresto Part 10 Value-Efficacy-15Jul08.pdf" deleted by Jamin Huang/MOAJ/US/BCS/BAYER] [attachment "2009-08-04 Sepresto efficacy data by Bill Striegel-BCS.pdf" deleted by Jamin Huang/MOAJ/US/BCS/BAYER]

\*\*\*\*\*  
Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

Jamin Huang/MOAJ/US/BCS/BAYER

08/05/2009 10:13 AM

To "Meredith Laws" <Laws.Meredith@epamail.epa.gov>  
cc Roy Lidstone/CSLIR/CA/BCS/BAYER@BAYER-CANADA-NOTES, "Kable "Bo" Davis"  
<Davis.Kable@epamail.epa.gov>  
Subject Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call [Link](#)

Good morning, Meredith, I am out of office today. I could e-mail you the Part 10 and some new efficacy data tomorrow. I will also compile a comparative table to respond your questions in the 3rd paragraph early next week. Best Regards, Jamin

----- Original Message -----  
From: Laws.Meredith  
Sent: 08/04/2009 03:49 PM AST



To: Jamin Huang  
 Cc: Roy Lidstone; Davis.Kable@epamail.epa.gov  
 Subject: Re: Sepesto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call

Hi Jamin -

Thank you for following up on the cucurbit residue data, we will look forward to receiving it.

I have a couple of questions on the efficacy issues. First, it appears that EPA did not receive the efficacy data that PMRA evaluated. Please send us that original package as soon as possible. I do not see it on the transmittal document. I thought that under Joint Reviews, both countries are to receive the same application package, but maybe that was originally intended only for new chemicals. We do want to see this data.

I also have a question on stand alone imidacloprid seed treatments - ie. those products that contain only imidacloprid. I thought that you had said in the meeting that the two neonicotinoids were combined because the efficacy for each on its own was poor or not very good. I had asked what that meant for the products that contained only one of the actives. I thought you had indicated that there are no products registered for these particular vegetable crops. Maybe I misunderstood. This is correct for clothianidin but our database shows 14 imidacloprid seed treatment products for carrots, 5 of these are Bayer's. We also have a Bayer product containing imidacloprid for seed treatment of squash and another one for seed treatment of squash, cucurbits, tomato and peppers. So if these products have the same target pests as the ones on the Sepesto label, and are at comparable imidacloprid rates, we have a concern for their product performance. We will have to make these comparisons and will also check the competitor's products. I expect they relied on Bayer data. Anyway, if the rates on the stand alone products are higher, we probably don't have an issue.

Please send us the efficacy data as soon as possible,

thank you,  
 Meredith

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|----->
| From: |
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>-----|
|Jamin Huang <jamin.huang@bayercropscience.com>
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| To: |
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>-----|
|Meredith Laws/DC/USEPA/US@EPA
|
>-----|
|----->
| Cc: |
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>-----|
|Roy Lidstone <roy.lidstone@bayercropscience.com>
|
>-----|
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Date: |

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>-----

|07/30/2009 11:38 AM

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|Subject: |

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|Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call

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|----->

Good morning, Meredith,

This email is to follow up with some of the questions raised in our joint EPA-PMRA-BCS conference call about Sepresto on 7/23. There are three questions that we would like to address.

1. Residues in nectar and pollen: BCS Global has conducted two GLP studies in Spain to measure the amount of residues in pollen and nectar from melon and sweet pepper plants grown from seeds treated with Sepresto 75 WS at the proposed US use rates. The samples collected will be analyzed for residues of clothianidin and imidacloprid. Most of the analytical data are expected to be available by the end of August. Once we have completed the analyses, we will present the data to both EPA and PMRA.

2. Need for two CNIs: Trials were conducted to evaluate the efficacy of Sepresto compared to clothianidin or imidacloprid individually. As an example, thrips and maggots are common pests in onions that the grower needs to control. Trials in onions were conducted to evaluate the control of thrips and maggots by Sepresto compared to clothianidin and imidacloprid alone. By combining the two active ingredients, the grower can get better control of both pests at total pesticide rates equal to or less than either ai alone. This example demonstrates that the combination of the two active ingredients (imidacloprid and clothianidin) can result in more effective control of these key onion pests at a total CNI application rate equal to or less than that of the individual chemicals. We plan to reorganize the data in Part 10 submitted to PMRA in August 2008 (as part of the Sepresto submission package to PMRA) to more effectively demonstrate the need for both CNIs in Sepresto.

3. Available efficacy data: This conference call might have given an impression that we do not have a lot of efficacy data for Sepresto. However, earlier work with prototype formulations containing clothianidin and/or imidacloprid, and more recent work with the Sepresto 75 WS formulation have been used to justify all label claims. Additional trials conducted in 2008 and 2009 with Sepresto 75WS have supported many of our originally proposed use rates. These data have not been reviewed by PMRA because they became available only after the submission of Sepresto last August.

We would like the opportunity to present you and your colleagues in BEAD with summaries of additional and re-worked efficacy data and summaries of our findings of residues in pollen and nectar. Please let us know if you have any additional questions.

Best Regards,



Jamin

\*\*\*\*\*

Jamin Huang, Ph.D.  
Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

The information contained in this e-mail is for the exclusive use of the intended recipient(s) and may be confidential, proprietary, and/or legally privileged. Inadvertent disclosure of this message does not constitute a waiver of any privilege. If you receive this message in error, please do not directly or indirectly use, print, copy, forward, or disclose any part of this message. Please also delete this e-mail and all copies and notify the sender. Thank you.

For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>





September 1, 2009

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

resubmission  
9-1-09

**ATTENTION:** Kable Bo Davis (RD, Insecticide-Rodenticide Branch))

**Re: Revised CSF for Sepresto 75 WS (EPA File Symbol 264-RNIR)**

Dear Mr. Davis,

Per your recent request to delete (N=56.25%) and (N=18.75%) from the draft CSF for Sepresto 75 WS dated 07/03/2008, we are herein submitting one copy of amended CSF dated 08/31/2009.

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding this CSF.

Sincerely,

Jamin Huang, Ph.D.  
Product Registration Manager

Attachment





Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call  
 Jamin Huang  
 to:  
 Meredith Laws  
 08/06/2009 06:38 AM  
 Cc:  
 Kable Davis, Roy Lidstone  
 Show Details

resubmission  
 8-6-09

Good morning, Meredith,

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Best Regards,  
 Jamin

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Jamin Huang, Ph.D.  
 Registration Product Manager  
 Bayer CropScience

tel: 919-549-2634  
 e-mail: jamin.huang@bayercropscience.com

Jamin Huang/MOYAJ/US/BCS/BAYER

08/05/2009 10:13 AM

To "Meredith Laws" <Laws.Meredith@epamail.epa.gov>  
 cc Roy Lidstone/CSLIR/CA/BCS/BAYER@BAYER-CANADA-NOTES, "Kable "Bo"  
 Davis" <Davis.Kable@epamail.epa.gov>  
 Subject Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference  
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----- Original Message -----  
 From: Laws.Meredith  
 Sent: 08/04/2009 03:49 PM AST  
 To: Jamin Huang



Cc: Roy Lidstone; Davis.Kable@epamail.epa.gov

Subject: Re: Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call

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Please send us the efficacy data as soon as possible,

thank you,  
Meredith

|----->  
| From: |  
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|----->  
| Jamin Huang <jamin.huang@bayercropscience.com> |  
|----->

|----->  
| To: |  
|----->

|----->  
| Meredith Laws/DC/USEPA/US@EPA |  
|----->



Cc:

Roy Lidstone <roy.lidstone@bayercropscience.com>

Date:

07/30/2009 11:38 AM

Subject:

Sepresto - follow-up of our 7/23 EPA-PMRA-BCS joint conference call

Good morning, Meredith,

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submitted to PMRA in August 2008 (as part of the Sepresto submission package to PMRA) to more effectively demonstrate the need for both CNIs in Sepresto.

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Best Regards,  
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Registration Product Manager  
Bayer CropScience

tel: 919-549-2634  
e-mail: jamin.huang@bayercropscience.com

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For alternate languages please go to <http://bayerdisclaimer.bayerweb.com>



Bayer CropScience



January 25, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

*Not put into  
OPPIW as  
resubmission*

**ATTENTION:** Venus Eagle (PM 01)

**Re: Sepresto 75 WS (EPA File Symbol: 264-RNIR)**

**Submission of Two Study Reports about Residues in Pollen and  
Nectar from the Seeds Treated with Sepresto 75 WS**

Dear Ms. Eagle,

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Bayer CropScience is herein submitting two final study reports with the residue data of imidacloprid, clothianidin and the relevant metabolites in whole flower, nectar and pollen grown from melon seeds, and in whole flower grown from sweet pepper seeds, treated with Sepresto 75 WS at the proposed use rates in the US.

We e-mailed the available residue data from preliminary analysis of these two studies to the Agency on September 7, 2009. The preliminary results indicated the risk to bees from Sepresto 75 WS treated melon seeds and sweet pepper seeds at the proposed rates to be very low. The final reports being submitted do not alter our previous conclusions.

As stated in the interim summary report on September 7, 2009, these studies demonstrate that the residue levels of clothianidin, imidacloprid and relevant metabolites in flowers grown from seeds treated with Sepresto are low, and all are well below the NOAEC for bees (20 ppb). In addition, the melon study demonstrates that the levels found in nectar and pollen are negligible, indicating that measuring whole flowers will tend to overestimate the actual exposure of bees to neonicotinoids from this seed treatment. The overall conclusion from these studies is that this seed treatment does not pose significant risk to bees.



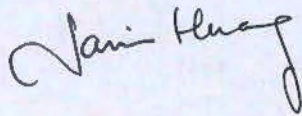
M-362163-01-1

**E-SUBMISSION**



Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding these two study reports.

Sincerely,

A handwritten signature in black ink, appearing to read "Jamin Huang". The signature is fluid and cursive, with the first name "Jamin" and last name "Huang" clearly distinguishable.

Jamin Huang, Ph.D.  
Senior Regulatory Manager



Bayer CropScience

**TRANSMITTAL DOCUMENT****Clothianidin & Imidacloprid****Sepresto 75 WS (264-RNIR): Residue Reports In Pollen and Nectar From Seeds****Transmittal Date**

January 25, 2010

Company Official:

Company Name:

Bayer CropScience

Company Contact:

Jamin Huang

Company Telephone:

+1 919 549 2634

**E-SUBMISSION**2 T.W. Alexander Drive  
RTP, NC 27709  
USA

M-362164-01-1



## **BIBLIOGRAPHY OF SUBMITTED DATA**

<b>Study No.</b>	<b>Study</b>	<b>Guideline No.</b>	<b>EPA MRID No.</b>
1	Transmittal Document	NGL	47961200
<b>REPORTS Non-Guideline Studies</b>			
<b>NGL Sweet Pepper Following Application of Sepresto 75 WS</b>			
2	Boksch, S.; Determination of residues of clothianidin and imidacloprid and their metabolites in sweet pepper following an application of clothianidin & imidacloprid WS 56.25 + 18.75 as seed treatment; Eurofins GAB GmbH, Niefern-Oeschelbronn, Germany; Report No.: S08-01368; Document No.: M-361762-01-1; January 11, 2010; Pages: 129	NGL	47961201
<b>NGL Melon Following Application of Sepresto 75 WS</b>			
3	Boksch, S.; Determination of residues of clothianidin and imidacloprid and their metabolites in melon following an application of clothianidin & imidacloprid WS 56.25 + 18.75 as seed treatment; Eurofins GAB GmbH, Niefern-Oeschelbronn, Germany; Report No.: S08-01369; Document No.: M-361798-01-1; January 11, 2010; Pages: 195	NGL	47961202



The following were received as part of an e-Submission. The documents are available electronically in OPP's Document Repository.

- |   |   |                                    |
|---|---|------------------------------------|
| <input type="checkbox"/> Active Ingredient              | <input type="checkbox"/> New registration | <input type="checkbox"/> Amendment |
| <input checked="" type="checkbox"/> Section 3 (end use) | <input type="checkbox"/> New registration | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Tolerance Petition             | <input type="checkbox"/> New registration | <input type="checkbox"/> Amendment |
| <input type="checkbox"/> EUP                            | <input type="checkbox"/> New registration | <input type="checkbox"/> Amendment |

Re-Submission

Qty: \_\_\_\_\_

Company Number:

264-RNIR

Receipt Date:

1/28/2010

Admin Number:

264-RNIR

Receipt Number:

866419

Root MRIDs:

479612

Number of Documents:

2

Comments:

Admin Number:

Receipt Number:

Root MRIDs:

Number of Documents:

Comments:

Admin Number:

Receipt Number:

Root MRIDs:

Number of Documents:

Comments:

Admin Number:

Receipt Number:

Root MRIDs:

Number of Documents:

Comments:



PM 1

# FAST-TRACK AMENDMENTS-Completeness Screening Checklist

Experts In-Processing Signature: SHI

EPA Reg. Number: 264-PNIR

EPA Receipt Date: 1/28/10

	Check List Item	Yes	No	NA
1	Application Form (EPA Form 8570-1) -signed?			X
2	Confidential Statement of Formula (EPA Form 8570-29) - signed?			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) signed?			
4	Formulator's Exemption Statement (EPA Form 8570-27) - signed?			
5	Data Matrix (EPA Form 8570-35) [Applicable, for adding me-too uses]			
	a) Selective Method?			
	b) Cite-All Method? Applicant owns data or list only the companies offered to pay			
	c) Public copy of Matrix provided? See PR Notice 98-5			
6	Is Label Included? (5 copies)			
	Comments: Data requested by Agency to support new product. E-submission			

Submitted to Candu too. Roy forwarded to PMR.



Receipt for Section 3					
S:	666419	Resubmission:	<input checked="" type="radio"/> Yes <input type="radio"/> No		
Regulatory Type:	Product Registration - Section 3	Fee For Service:	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Application Type:	New Registration	Billable:	<input type="radio"/> Yes <input checked="" type="radio"/> No		
Company:	264 BAYER CROSCIENCE LP		V		
Risk Manager:	Registration Division, Risk Management Team 1				
Product #:	264-RNIR	Product Name:	Sepresto 75 WS		
Override#:					
Me Too Section3:		Me Too Product Name:			
Application Date:	25-Jan-2010	icd	OPP Rec'vd Date:	28-Jan-2010	icd
Front End Date:	28-Jan-2010	icd	Risk Manager Send Date:	22-Feb-2010	icd
FFS Due Date:			Negotiated Due Date:		
OPP Target Date:					
Fast Track:	<input type="checkbox"/>	New Ingredient:	<input type="checkbox"/>		
Receipt Description:					
Associated with e-Submission package #1571. Submission of studies to support the new product.					
Form A:	<input type="checkbox"/>	Signature Date:		Form B:	<input type="checkbox"/>
				View/Edit	
				New Ingredient Request Date:	
				New Ingredient Received Date:	
				Signature Date:	

Print Letter

Enter More Information

Tracking

Receipt Content	Des
Study	





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 22, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MARGARET CHERNY  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, PO Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

PRODUCT NAME: Sepresto 75 WS  
COMPANY NAME: BAYER CROPSCIENCE LP  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 264-RNIR  
EPA RECEIPT DATE: 01/28/10

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

*P. F. Rosen*  
Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



**Fee for Service**

{866419E~

This package includes the following

- ☐ New Registration
- ☒ Amendment

☒ Studies?      ☐ Fee Waiver?  
☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S-

866419

EPA File Symbol/Reg. No.

264-RNIR

Pin-Punch Date:

1/28/2010

☒ This item is NOT subject to FFS action.

**E-SUBMISSION**

Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_

Parent/Child Decisions:

☐ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *He Bo*

Date: 2-18-10

Remarks:

*Data requested by the Agency*



E - Submission



**Memorandum**

264-RNIR

Date: 2 / 22 / 10

To: PM 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a:

- ☒ fully accepted submission
- ☐ partially accepted submission
- ☐ rejected submission





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

February 22, 2010

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES


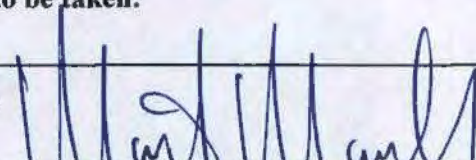
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE, PO Box 12014  
RESEARCH TRIANGLE PARK, NC 27709

Report of Analysis for Compliance with PR Notice 86-5

Thank you for your submittal of 28-JAN-10. Our staff has completed a preliminary analysis of the material. The results are provided as follows:

Your submittal was found to be in full compliance with the standards for submission of data contained in PR Notice 86-5. A copy of your bibliography is enclosed, annotated with Master Record ID's (MRIDs) assigned to each document submitted. Please use these numbers in all future references to these documents. Thank you for your cooperation. If you have any questions concerning this data submission, please raise them with the cognizant Product Manager, to whom the data have been released.



Recommendation of Division Directors Negotiated Due Dates		
<b>Decision#:</b> 399491, 399489, 399569, 399584, 399585, 399586	<b>Registration#:</b> 264-755, 264-827, 264-RNIR	<b>Petition #:</b> 8F7414, 8F7415
<b>Fee Category:</b> 399491 (R170.2), 399489 (R310), 399569 (R170.0), 399584 (R170.0), 399585 (R274), 399586 (R274.0)	<b>PRIA Decision Time Frame:</b> 15 months	
<b>Submitted by:</b> Kable Bo Davis	<b>Branch:</b> RD/IRB	<b>Date:</b> April 1, 2010
Bayer CropScience		
<b>Original Due Date:</b> February 1, 2010	<b>Proposed New Due Date:</b> May 1, 2010	
<b>Previous Negotiated Due Dates:</b> April 1, 2010		
<b>Is the "Fix" in-house?</b> yes	<b>If not, date "Fix" expected:</b>	
<b>Issue (describe in detail):</b> This action concerns formulations adding two neonicotinoids (imidacloprid and clothianidin). Additional time is needed to consider potential pollinator issues. This submission is being elevated to the Office Director.		
<b>Summary of Deficiency Type(s):</b> <b>Not Submitted (N)</b> <b>Deficiencies (D)</b> <b>Product Chemistry:</b> ___ <b>Acute Tox:</b> ___ <b>Efficacy:</b> ___ <b>Labeling:</b> ___ <b>Other?:</b> <u>  X  </u>		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> <u>Thursday, April 1, 2010</u> : The registrant was informed via phone call that a renegotiation would be necessary. The registrant forwarded, via email, a letter requesting the renegotiation.		
<b>"75 Day" Letter sent?</b> _____ <b>(Date sent)</b> Yes <u>  X  </u> <b>No and reason for none?</b> Not applicable in this case. Application is not deficient.		
<b>Rationale for Proposed Due Date:</b> Additional time is needed to consider potential pollinator issues. This submission is being elevated to the Office Director.		
<b>Registrant notified that this is the last negotiation?</b> Yes <u>  X  </u> <b>Not Applicable</b>		
<b>Approve:</b> 	<b>Disapprove:</b>	
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> 	<b>Date:</b> 4-1-10	

Revised May 2007



Bayer CropScience



April 1, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

ATTENTION: Kable Bo Davis (RD, Insecticide-Rodenticide Branch)

**Re: Imidacloprid**  
**D-399586 (PP 8F7415)**  
**D-399584 (PP 8F7414)**  
**D-399489 (Sepresto 75 WS, 264-RNIR)**  
**D-399585 (Imidacloprid technical, 264-755)**  
**D-399491 (Imidacloprid technical, 264-755)**  
**D-399569 (Gaucho 550 SC, 264-827)**

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Dear Mr. Davis,



Bayer CropScience agrees to renegotiate the PRIA due dates for the imidacloprid-related subject decision numbers as follows in order to receive a decision on Sepresto 75 WS (EPA File Symbol: 264-RNIR), Gaucho 550 SC (EPA Reg. No. 264-827) and Imidacloprid technical (EPA Reg. No. 264-755) by May 1, 2010. This extension would allow the Agency additional time to complete the current assessments of imidacloprid.

Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding these re-negotiated PRIA due dates.

Sincerely,

Jamin Huang, Ph.D.  
Senior Regulatory Manager



Recommendation of Division Directors Negotiated Due Dates		
<b>Decision#:</b> 399491, 399489, 399569, 399584, 399585, 399586	<b>Registration#:</b> 264-755, 264-827, 264-RNIR	<b>Petition #:</b> 8F7414, 8F7415
<b>Fee Category:</b> 399491 (R170.2), 399489 (R310), 399569 (R170.0), 399584 (R170.0), 399585 (R274), 399586 (R274.0)	<b>PRIA Decision Time Frame:</b> 15 months	
<b>Submitted by:</b> Kable Bo Davis	<b>Branch:</b> RD/IRB	<b>Date:</b> January 27, 2010
Bayer CropScience		
<b>Original Due Date:</b> February 1, 2010	<b>Proposed New Due Date:</b> April 1, 2010	
<b>Previous Negotiated Due Dates:</b> Varies per		
<b>Is the "Fix" in-house?</b> yes	<b>If not, date "Fix" expected:</b>	
<b>Issue (describe in detail):</b> This action concerns the establishment of imidacloprid tolerances for several different commodities. Additional time is required to allow the Agency time to respond to comments submitted by NRDC. In addition, additional time is needed to publish the Final Rule due to late changes being made to the risk assessment (i.e., bed bugs were added to the assessment at the request of the registrant).		
<b>Summary of Deficiency Type(s):</b> <b>Not Submitted (N)</b> <b>Deficiencies (D)</b> <b>Product Chemistry:</b> ___ <b>Acute Tox:</b> ___ <b>Efficacy:</b> ___ <b>Labeling:</b> ___ <b>Other?:</b> <u>  X  </u>		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> <u>Monday, January 25, 2010:</u> The registrant was informed via phone call that a renegotiation would be necessary. <u>Tuesday, January 26, 2010:</u> The registrant forwarded, via email, a letter requesting the renegotiation.		
<b>"75 Day" Letter sent?</b> _____ <b>(Date sent)</b> Yes <u>  X  </u> <b>No and reason for none?</b> Not applicable in this case. Application is not deficient.		
<b>Rationale for Proposed Due Date:</b> The additional time will allow RD to revise the final rule per the revised risk assessment, and to respond to NRDC comments.		
<b>Registrant notified that this is the last negotiation?</b> Yes <u>  X  </u> <b>Not Applicable</b>		
<b>Approve:</b> 	<b>Disapprove:</b>	
<b>If disapproved, action to be taken:</b>		
<b>OD or DOD Signature:</b> 	<b>Date:</b> 1-28-10	

Revised May 2007



Bayer CropScience



January 26, 2010

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

ATTENTION: Kable Bo Davis (RD, Insecticide-Rodenticide Branch)

**Re: Clothianidin and Imidacloprid**

D-399566 (PP 8F7413)  
D-399488 (PP 8F7416)  
D-399486 (PP 8F7417)  
D-399586 (PP 8F7415)  
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D-399489 (Sepresto 75 WS, 264-RNIR)  
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D-399491 (Imidacloprid technical, 264-755)  
D-399569 (Gaucho 550 SC, 264-827)

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Dear Mr. Davis,

Bayer CropScience agrees to renegotiate the PRIA due dates for the imidacloprid-related subject decision numbers as follows in order to receive a decision on Sepresto 75 WS (EPA File Symbol: 264-RNIR), Gaucho 550 SC (EPA Reg. No. 264-827) and Imidacloprid technical (EPA Reg. No. 264-755) by April 1, 2010. This extension would allow the Agency additional time to complete the current assessments of imidacloprid. Since Proceed Optimum (EPA File Symbol: 264-RNIE) does not contain imidacloprid, its February 1, 2010 PRIA due date remains unchanged.

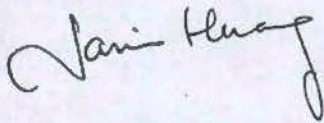
D-399566 (PP 8F7413) - from Dec. 17, 2009 to February 1, 2010 (no change, related to clothianidin)  
D-399488 (PP 8F7416) - from Dec. 13, 2009 to February 1, 2010 (no change, related to clothianidin)  
D-399486 (PP 8F7417) - from Dec. 4, 2009 to February 1, 2010 (no change, related to clothianidin)



D-399586 (PP 8F7415) - *from February 1, 2010 to April 1, 2010*  
D-399584 (PP 8F7414) - *from February 1, 2010 to April 1, 2010*  
D-399489 (Sepresto 75 WS, 264-RNIR) - *from February 1, 2010 to April 1, 2010*  
D-399587 (Proceed Optimum, 264-RNIE) – *stay on February 1, 2010 (no change, related to clothianidin)*  
D-399585 (Imidacloprid technical, 264-755) - *from February 1, 2010 to April 1, 2010*  
D-399491 (Imidacloprid technical, 264-755) - *from February 1, 2010 to April 1, 2010*  
D-399569 (Gaucho 550 SC, 264-827) - *from February 1, 2010 to April 1, 2010*

Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding these re-negotiated PRIA due dates.

Sincerely,



A handwritten signature in black ink, appearing to read "Jamin Huang". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

Jamin Huang, Ph.D.  
Senior Regulatory Manager



Recommendation of Division Directors Negotiated Due Dates		
<b>Decision#:</b> 399489, 399587, 399491, 399585, 399569, 399566, 399584, 399586, 399488, 399486	<b>Registration#:</b> 264-RNIR (399489) 264-RNIE (399587) 264-755 (399491 & 399585) 264-827 (399569)	<b>Petition #:</b> 8F7413 (399566) 8F7414 (399584) 8F7415 (399586) 8F7416 (399488) 8F7417 (399486)
<b>Fee Category:</b> (categorized by decision number) 399489 (R310), 399587 (R190.1), 399491 (R170.2), 399585 (R274), 399569 (R170.0), 399566 (R190.0), 399584 (R170.0), 399586 (R274.0), 399488 (R292), 399486 (R295)		<b>PRIA Decision Time Frame:</b> varies depending upon PRIA code
<b>Submitted by:</b> Kable Bo Davis	<b>Branch:</b> IRB	<b>Date:</b> 12/03/09
<b>Company:</b> Bayer CropScience		
<b>Original Due Date:</b> 399489 (3/10/09), 399587 (12/17/09), 399491 (12/13/09), 399585 (9/14/09), 399569 (12/13/09), 399566 (12/17/09), 399584 (12/13/09), 399586 (12/13/09), 399488 (12/13/09), 399486 (12/4/09)	<b>Proposed New Due Date:</b> February 1, 2010	
<b>Previous Negotiated Due Dates:</b> 264-RNIR (399489) has already been renegotiated to 12/13/09; 264-755 (399585) has already been renegotiated to 12/13/09		
<b>Is the "Fix" in-house?</b> yes	<b>If not, date "Fix" expected:</b>	
<b>Issue (describe in detail):</b> The registrations of all of these actions have been slowed due to Agency pollinator concerns and the publication of Federal Register Documents.		
<b>Summary of Deficiency Type(s):</b> Not Submitted (N) Deficiencies (D) <b>Product Chemistry:</b> ___ <b>Acute Tox:</b> ___ <b>Efficacy:</b> ___ <b>Labeling:</b> ___ <b>Other?:</b> <u>X</u>		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> The Agency and Bayer CropScience have had multiple meetings and conference calls over the last 12+ months concerning potential pollinator concerns for neonicotinoid seed treatment products, including the proposed products. <b>December 2, 2009-</b> The Agency called Bayer CropScience and explained the necessity for renegotiating the PRIA due dates for the pending products. <b>December 3, 2009-</b> Bayer CropScience emailed the Agency a signed letter requesting the renegotiations.		



<b>"75 Day" Letter sent?</b> <u>      </u> (Date sent) <b>Yes</b> <u><b>X</b></u> <b>No and reason for none?</b>	
A "75 Day" letter was not sent to Bayer CropScience because there aren't any deficient documents needed from the registrant.	
<b>Rationale for Proposed Due Date:</b> This renegotiation is necessary to allow the Agency time to discuss potential pollinator issues associated with these registrations (neonicotinoid seed treatment products). In addition, this renegotiation will provide the time necessary to publish the Final Rules.	
<b>Registrant notified that this is the last negotiation?</b> <b>Yes</b> <u><b>X</b></u> <b>Not Applicable</b>	
<b>Approve:</b> 	<b>Disapprove:</b>
<b>If disapproved, action to be taken:</b>	
<b>OD or DOD Signature:</b> 	<b>Date:</b> 12-3-09

Revised May 2007



Bayer CropScience



December 3, 2009

Document Processing Desk  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

ATTENTION: Kable Bo Davis (RD, Insecticide-Rodenticide Branch)

**Re: Clothianidin and Imidacloprid**

D-399566 (PP 8F7413)  
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Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Dear Mr. Davis,

Bayer CropScience agrees to renegotiate the PRIA due dates for the subject decision numbers as follows in order to receive a decision on Sepresto 75 WS (EPA File Symbol: 264-RNIR), Proceed Optimum (EPA File Symbol: 264-RNIE), Gaucho 550 SC (EPA Reg. No. 264-827) and Imidacloprid technical (EPA Reg. No. 264-755) by February 1, 2010.

D-399566 (PP 8F7413) - *from Dec. 17, 2009 to February 1, 2010*  
D-399488 (PP 8F7416) - *from Dec. 13, 2009 to February 1, 2010*  
D-399486 (PP 8F7417) - *from Dec. 4, 2009 to February 1, 2010*  
D-399586 (PP 8F7415) - *from Dec. 13, 2009 to February 1, 2010*  
D-399584 (PP 8F7414) - *from Dec. 13, 2009 to February 1, 2010*  
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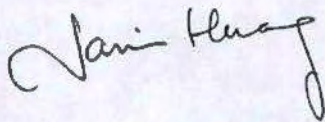
D-399585 (Imidacloprid technical, 264-755) - *from Dec. 13, 2009 to February 1, 2010*

D-399491 (Imidacloprid technical, 264-755) - *from Dec. 13, 2009 to February 1, 2010*

D-399569 (Gaucho 550 SC, 264-827) - *from Dec. 13, 2009 to February 1, 2010*

Please let me know at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) or at 919-549-2634 if you have any questions regarding these re-negotiated PRIS due dates.

Sincerely,

A handwritten signature in black ink, appearing to read "Jamin Huang". The signature is fluid and cursive, with a long, sweeping underline that extends to the right.

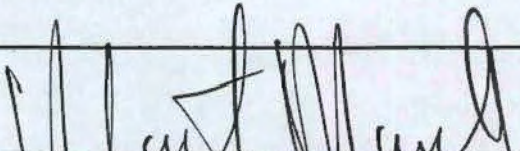
Jamin Huang, Ph.D.  
Product Registration Manager



**Recommendation of Division Directors  
Negotiated Due Dates**

<b>Decision #:</b> 1) D399489 2) D399488 3) D399586 4) D399585	<b>Registration #:</b> 1) 264-RNIR 2) Increase tolerance petition 3) Tolerances for seed treatment 4) 264-755	<b>Petition #:</b> 1) ----- 2) 8F7416 3) 8F7415 4) -----
<b>Fee Category:</b> 1) R310, 2) R292, 3) R274, 4) R274		<b>PRIA Decision Time Frame:</b> 1) 6mos., 2) 10mos., 3) 12mos., 4) 12mos.
<b>Submitted by:</b> Venus Eagle		<b>Branch:</b> IRB <b>Date:</b> 9/30/08
<b>Company:</b> Bayer Crop Science (BCS)		
<b>Original Due Date:</b> 1) 3/9/09 2) 7/7/09, 3) 9/14/09, 4) 9/14/09		<b>Proposed New Due Date:</b> 1 through 4 = 12/13/09 (15 months)
<b>Previous Negotiated Due Dates:</b> None		
<b>Is the "Fix" in-house?</b> N/A		<b>If not, date "Fix" expected:</b> N/A
<b>Issue (describe in detail):</b> Bayer has submitted a "global" systemic insecticide combination product for seed treatment use on vegetable and cereal grain seeds. This new submission/product is a 2 <sup>nd</sup> entry joint review project with PMRA. The end-use product contains two active ingredients for which several tolerance petitions were submitted. Therefore in an effort to coordinate the time frames with the other 7 actions submitted and in harmony with PMRA time frame, the registrant has agreed and requested a 15 month time frame (until 12/13/09) for all actions that do not currently have that PRIA time frame.		
<b>Summary of Deficiency Type(s):</b> Not Submitted (N)      Deficiencies (D) <b>Product Chemistry:</b> ____ <b>Acute Tox:</b> ____ <b>Efficacy:</b> ____ <b>Labeling:</b> ____ <b>Other (describe):</b> ____ No deficiencies at this point.		
<b>Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates):</b> 4/29/08 – 9/12/08: E:mails, phone calls and meetings to discuss the appropriate PRIA fees and time line for the 11 actions submitted which total over 800,000 dollars.		
<b>"75 Day" Letter sent?</b> ____ (Date sent) Yes <input checked="" type="checkbox"/> No and reason for none? The submission was just received and the registrant is proactively requesting a time extension for all actions that do not have a time frame of 15 months.		



<b>Rationale for Proposed Due Date:</b> See explanation above under Issue.	
<b>Registrant notified that this is the last negotiation?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not Applicable	
<b>Approve:</b> <input checked="" type="checkbox"/>	<b>Disapprove:</b> <input type="checkbox"/>
<b>If disapproved, action to be taken:</b>	
<b>OD or DOD Signature:</b> 	<b>Date:</b> 10-3-08



## Imidacloprid Notice of Receipt: Response to Comments

### **NRDC Comment: Pollinators - residue and chronic exposure studies are needed**

In its Final Work Plan for the registration review of imidacloprid, EPA anticipated needing the following pollinator studies to conduct an ecological risk assessment: 1) a field test for pollinators using TEP imidacloprid (GLN 850.3040); and 2) a repeat dose field study for pollinators (special study). EPA must require that the registrants submit these studies before proceeding to evaluate the Registration Application for new uses. It is also critical that any studies submitted by the registrants be properly designed to ensure that data needs concerning the chronic toxicity of imidacloprid are met. Based on a review of published literature on imidacloprid and the EPA May 2007 Risk Assessment, NRDC has identified a need for the following studies:

- An analysis of imidacloprid concentration in the nectar and pollen of treated plants (including plants grown from imidacloprid-treated seed), plants grown in imidacloprid-treated soil, and untreated plants grown in soil previously planted with imidacloprid-treated plants; as well as imidacloprid in bee pollen and honey. An evaluation of plant metabolism should also be included, as suggested in the May 2007 Risk Assessment.
- A study on the effects of imidacloprid on bee behaviors such as grooming, navigation, learning, and foraging.
- A multi-generational field study analyzing chronic effects of imidacloprid on honey bees, and its effects on reproduction and brood development and survival.
- A study analyzing chronic effects of imidacloprid on multiple native bee species.

*EFED response: The Agency is currently coordinating efforts with the California Department of Pesticide Regulation and the Pesticide Management Regulatory Agency of Canada in order to request appropriately designed field residue studies that assess concentrations of imidacloprid in the nectar and pollen of a variety of treated plants. The Agency acknowledges the importance of using soil and seed treatments, plants grown in imidacloprid-treated soil, and untreated plants grown in soil previously planted with imidacloprid-treated plants. The Agency will also consider plant metabolism in the development of the field study design.*

*The Agency recognizes the importance of assessing sub-lethal effects such as learning and foraging, multi-generational field studies, and the relevance of these studies to native bee species. The Agency will pursue a field study that assesses whole hive parameters, including sub-lethal effects and impacts on the brood, as well as a field study design that adequately addresses chronic exposure of imidacloprid to bees. The assessment of imidacloprid will also rely on published literature according to current EFED policy on the incorporation of open literature in the evaluation of potential impacts to bees.*



*The NRDC also suggests conducting chronic studies on multiple native bee species. The Agency currently uses the honey bee, *Apis mellifera*, as a surrogate for assessing impacts on all non-target insect species. In addition, the EFED will review open literature related to the effects of imidacloprid on pollinators that may include information on pollinator species other than *A. mellifera* including native bee species.*

**NRDC Comment: Risks to aquatic species, birds and mammals**

Acute and chronic risk quotients (RQs) above the applicable level of concern (LOC) were identified for aquatic invertebrates from uses on peanuts, kava, millet, oat, soybeans, caneberry subgroup 13A, raspberry and artichoke. Chronic RQ's above the LOC were also identified for birds from single and multiple broadcast spray applications on peanuts, caneberry subgroup and artichoke. EPA must consider risk mitigation measures to reduce these risks and reject the registration of any uses for which RQ's cannot be mitigated to below the LOC.

*EFED response: When the Agency determines that risk to non-target organisms may result from a proposed use, it develops mitigation measures to ensure that unreasonable adverse effects to non-target organisms will not occur. The development of these measures is a cooperative effort between risk assessors and risk managers. Risk mitigation may be achieved in a number of ways, including establishment of buffer zones, classification of a product as restricted use, requirement of hazard statements on product labels, or cancellation of certain uses.*

*For imidacloprid products, EFED recommended environmental hazards labeling to protect nontarget organisms. The following is an example of environmental hazard labeling found on a representative imidacloprid product:*

*"Do not apply directly to water, areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.*

*This product is highly toxic to bees exposed to direct treatment or residues on blooming crops or weeds. Do not apply this product or allow it to drift to blooming crops or weeds if bees are visiting the treatment area. This product is toxic to wildlife and highly toxic to aquatic invertebrates."*

*Should future assessments indicate that the potential for unreasonable adverse effects still exists, additional mitigation measures will be considered.*

**NRDC Comment: Endocrine disruption risks are not properly considered**

The lack of a testing protocol under the Endocrine Disruptor Screening Program (EDSP) should not prevent EPA from requesting adequate studies on endocrine disruption in birds and mammals for the purpose of the registration review. A better characterization of these risks may result in changes to the risk quotients (RQs) obtained in the previous ecological risk assessment and may have implications for the endangered species assessment. EPA



must require that the registrants submit endocrine disruption studies before the Agency evaluates the Registration Application for new uses of imidacloprid.

*EFED response: As required under FFDCA section 408(p), EPA has developed the Endocrine Disruptor Screening Program (EDSP) to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach in making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.*

*Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. This list of chemicals was selected based on the potential for human exposure through pathways such as food and water, residential activity, and certain post-application agricultural scenarios. This list should not be construed as a list of known or likely endocrine disruptors.*

*Under FFDCA sec. 408(p) the Agency must screen all pesticide chemicals. Accordingly, EPA anticipates issuing future EDSP test orders/data call-ins for all pesticide active ingredients. Imidacloprid is among the group of 58 pesticide active ingredients on the initial list to be screened under the EDSP.*

*For further information on the status of the EDSP, the policies and procedures, the list of 67 chemicals, the test guidelines and the Tier 1 screening battery, please visit our website: <http://www.epa.gov/endo/>.*

**NRDC Comment: Risk assessment does not include imidacloprid degradates**

EPA has stated that "EFED is unable to rule out potential concerns for exposure to degradates of imidacloprid due to a lack of information on the fate and toxicity of these compounds." However, neither the Final Work Plan for the registration review nor the Notice on the Registration Application (74 Fed. Reg. 54999) mention any intention by EPA to require studies on the fate and toxicity of imidacloprid degradates. EPA should require these studies on imidacloprid degradates in soil and aquatic environments and integrate the information into its risk assessment before evaluating the Registration Application.

*EFED response: The Agency appreciates the comments from the NRDC regarding the analyses of the degradates and acknowledges that additional information on the fate and toxicity of the degradates is needed. Studies have been published on the toxicity of certain degradates in the open literature, and the Agency will consider these studies in its risk assessment of imidacloprid. In addition, the Agency is requesting residue studies on a number of different crops and will*



*require data to be collected on residues of the parent imidacloprid, as well as its degradates that have shown toxicity to pollinators, in order to better evaluate the potential risk to pollinators.*

**NRDC Comment: Need for a complete endangered species determination**

Previous imidacloprid risk assessments did not contain a complete endangered species determination. The EPA Final Work Plan for the registration review of imidacloprid indicates that the Agency plans to request a study on aerobic aquatic soil metabolism (GLN 835.4300), a Tier I seedling emergence study (GLN 850.4100), a Tier I vegetative vigor study (GLN 850.4150), a Tier I aquatic plant growth study, and a seed leaching study (special study), in addition to the pollinator studies mentioned previously. In addition to these studies, EPA should also include the studies on endocrine disruption and imidacloprid metabolites suggested above for developing the endangered species determination. EPA must do this before evaluating the Registration Application to ensure that risks to endangered species are properly accounted for and mitigated when necessary.

*EFED response: The pesticide ecological risk assessments for registration review will address Endangered Species Act Section 7(a)(2) obligations. The planned ecological risk assessment will evaluate the lines of evidence and make a determination of potential effects to endangered species. If the planned ecological risk assessment indicates that imidacloprid may affect, either directly or indirectly, listed species or affect critical habitat, the Agency will take steps to refine the assessment to determine whether the pesticide uses are likely to adversely affect, or are not likely to adversely affect, the species. In the case of critical habitat, the Agency will assess whether use of the pesticide may destroy or adversely modify any principle constituent elements for the critical habitat.*



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460



OFFICE OF PREVENTION, PESTICIDE  
AND TOXIC SUBSTANCES

**MEMORANDUM**

**Date:** January 20, 2010

**SUBJECT:** Imidacloprid; Response to comments on human health risks submitted by Mayra Quirindongo of the NRDC

**PC Code:** 129099  
**Decision No.:** NA  
**Petition No.:** NA  
**Risk Assessment Type:** NA  
**TXR No.:** NA  
**MRID No.:** NA

**DP Barcode:** D371978  
**Registration No.:** NA  
**Regulatory Action:** NA  
**Case No.:** NA  
**CAS No.:** NA  
**40 CFR:** NA

Ver.Apr.08

**FROM:** Robert Mitkus, PhD, DABT, Toxicologist  
Kelly Lowe, MS, Environmental Scientist  
Registration Action Branch 1  
Health Effects Division (7509P)

Handwritten signatures of Robert Mitkus and Kelly Lowe.

**THROUGH:** Dana Vogel, Branch Chief  
Registration Action Branch 1  
Health Effects Division (7509P)

Handwritten signature of Dana Vogel.

**TO:** Kable Davis  
Registration Division (7505P)

**I. CONCLUSIONS**

**Occupational risk assessment**

As indicated in the NRDC comment document (EPA-HQ-OPP-2008-0772), the Agency has completed a review of all registered uses of imidacloprid and resulting occupational exposure scenarios as part of Registration Review. All existing uses have been identified and a determination as to whether all possible exposure scenarios have been assessed has been



performed. For the proposed uses of imidacloprid, all potential occupational exposure scenarios will be assessed in the risk assessment document.

### **FQPA Safety Factor and DNT Study**

I. In a recent submission to the Agency, Ms. Quirindongo of the Natural Resources Defense Council argued that the FQPA Safety Factor (SF) for imidacloprid should be 10X rather than the values determined by the Agency. In her statement on p. 9, it appears that Ms. Quirindongo utilized two outdated assessments for imidacloprid (1997 and 1998) in formulating her opinion. However, two peer reviews of the toxicological database for imidacloprid took place after 1998 and these supersede any previous assessments. In 2002, the HED Hazard Identification Assessment Review Committee (HIARC) re-examined the FQPA SF and the potential for increased susceptibility of infants and children from exposure to imidacloprid. The peer-review committee concluded that the FQPA SF could be reduced to 1X based on several toxicological considerations. These include the following:

- There is no quantitative or qualitative evidence of increased susceptibility of rat fetuses to in utero exposure in developmental studies.
- There is no quantitative or qualitative evidence of increased susceptibility of rabbit fetuses to in utero exposure in developmental studies.
- There is no quantitative or qualitative evidence of increased susceptibility of rat offspring in the multi-generation reproduction study.
- There is evidence of increased qualitative susceptibility in the rat developmental neurotoxicity study. However, the concern is low since 1) any effects in pups are well-characterized with clear NOAELs; 2) any pup effects occur in the presence of maternal toxicity with the same NOAEL for effects in both pups and dams; and 3) the doses and endpoints selected for regulatory purposes are protective of the pup effects noted at higher doses in the developmental neurotoxicity study.
- There are no residual uncertainties for pre-/post-natal toxicity in the toxicological database for imidacloprid.

II. On p. 10 of her submission, Ms. Quirindongo correctly states that a developmental neurotoxicity (DNT) study was submitted for imidacloprid and that the results should be highly regarded. In fact, the results of the DNT study were utilized by the HIARC in 2002 to arrive at the committee's scientific conclusion that the FQPA SF should be reduced to 1X. In the study, toxicity was observed in both maternal animals and offspring at the same dose (the high dose), and clear NOAELs were obtained for both offspring and maternal animals. Measurement of the caudate/putamen at the mid dose was requested by the Agency for females only; however, there is no scientific reason to believe that the caudate/putamen width at the mid dose in females would be any different from control values, since this measurement was unaffected in males and there is no evidence in the study that females are more sensitive than males; since the change in



caudate/putamen width at the high dose in females was very small (only 2%); and since there was no effect on brain weight or on any other morphometric or structural measurement in either sex. Because the biological significance of such a small change is equivocal, its use as an endpoint to set the LOAEL in the study is considered highly conservative.

III. On p. 12 of her submission, Ms. Quirindongo correctly noted that the acute dietary exposure endpoint was based on a study (acute neurotoxicity study) that had a LOAEL but no NOAEL; however, she incorrectly states that the Agency failed to apply a conventional 3X adjustment: "EPA has conventionally applied an additional 3X adjustment factor when it relies on a study in which a no-effect level cannot be established... In this case, however, EPA did not follow convention...." In fact, the Agency did apply a conventional 3X adjustment factor to this point of departure. Specifically, a 3X FQPA SF was applied in the form of a LOAEL-to-NOAEL extrapolation factor ( $UF_L$ ) for this exposure scenario. This decision was based not only on convention but primarily on the following scientific observations that took the entire toxicological database into consideration:

- 1) the LOAEL in the study (42 mg/kg) is comparable to or lower than the LOAELs seen in adults in the developmental toxicity study in rat (30 mg/kg/d) and the two-generation reproductive toxicity study [47/52 mg/kg/d (male/female)] and in offspring in the DNT study (55 mg/kg/d).
- 2) the extrapolated NOAEL of 14 mg/kg ( $42/3X = 14$ ) is lower than the NOAEL of 20 mg/kg/d established in offspring in the DNT study and therefore protective of any offspring toxicity observed at higher doses in the DNT study.
- 3) the effects in this study showed a good dose response which resulted in *minimal* and *statistically non-significant* effects on motor activity and locomotor activity in one sex at the LOAEL.

For these reasons, therefore, the Agency is confident that the 3X uncertainty factor applied to the acute dietary exposure endpoint results in an *acute* reference dose that is protective of the offspring toxicity that was observed at doses that were approximately 400 times higher in the DNT study. It is also noted that the *chronic* reference dose is also protective of the offspring toxicity that was observed at doses that were approximately 1000 times higher in the DNT study.

IV. On p. 14, Ms. Quirindongo states "many possible adverse impacts are not tested for or considered by EPA." EPA disagrees with this statement. Current law for food-use pesticides, such as imidacloprid, requires a complete battery of at least 22 GLP studies in animals that assess a full range of potential toxicities. These include acute, subchronic, chronic, developmental, and reproductive toxicities, as well as neurotoxicity, immunotoxicity, carcinogenicity, mutagenicity, and chromosomal damage. In addition, with the implementation of the endocrine disruptor screening program, possible interactions of a given compound with the estrogen, androgen, and thyroid hormone systems are also being tested. All of the required toxicity studies, which are performed in 4 species, assess effects in all of the many organs and organ systems that are possible targets of toxicity in both adult and young animals, thereby providing a full picture of the hazard potential of each pesticide. In the case of imidacloprid,



such a comprehensive assessment of toxicity has allowed EPA to assess with confidence that there is a reasonable certainty of no harm to humans following its use on vegetable, bulb, and cereal grain.

## **II. ACTION REQUESTED**

Please address the comments made by NRDC regarding human health risks for imidacloprid.



## RESIDUE REVIEW

**PRODUCT:** Sepresto 75 WS

**FILE SYMBOL:** 264-RNIR

**DATE:** April 13, 2010

**GLP:** Yes

**BARCODE:** D376445

**DECISION:** 399489

**CHEMICAL:** clothianidin (56.25%)  
imidacloprid (18.75%)

**CHEMICAL NUMBER:** clothianidin; 044309  
imidacloprid; 129099

**PURPOSE:** Data submitted concerning residues of clothianidin and imidacloprid in melons and peppers grown from treated seed.

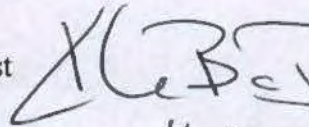
**MRIDS:** 47961201. Bocksch, S. (2010) *Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Sweet Pepper following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361762/01/1, S08/01368, M/361762/01/2/OCR. Unpublished study prepared by Eurofins – GAB GmbH. 130 p.*

47961202. Bocksch, S. (2010) *Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Melon following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361798/01/1, S08/01369, M/361798/01/2/OCR. Unpublished study prepared by Eurofins- GAB GmbH. 196 p.*

**TEAM REVIEWER:** Kable Bo Davis

**SCIENCE REVIEWER:** Kable Bo Davis, M.S., Entomologist

**SECONDARY SCIENCE REVIEWER:** Meredith F. Laws, M.S., Branch Chief  
Entomologist



4-13-10



## BACKGROUND:

Sepresto 75 WS (EPA File Symbol 264-RNIR) is a systemic insecticide seed treatment intended for use on numerous vegetable and cereal commodities. The Directions for Use include varying rates depending upon commodity (see Table 1). In addition, the proposed label includes the restriction "*Regardless of the type of application (seed treatment, soil, or foliar) do not apply more than a total of 6 oz. clothianidin and 8 oz. imidacloprid per acre pre cropping cycle.*"

On January 25, 2010, Bayer CropScience submitted MRID numbers 47961201 and 47961202 in an attempt to address the Agency's concern regarding potential risk to pollinators.

**Table 1. Proposed Rates<sup>1</sup>**

Commodity	Proposed Rate
Melon	0.995 g clothianidin per 1000 seeds 0.33 g imidacloprid per 1000 seeds
Sweet Pepper	0.495 g clothianidin per 1000 seeds 0.165 g imidacloprid per 1000 seeds

<sup>1</sup> only rates for melon and peppers

## DATA REVIEW:

The following data review is comprised of explanations of materials and methods, and a summation of experimental results containing tables with reformatted data.

**47961201. Bocksch, S. (2010) Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Sweet Pepper following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361762/01/1, S08/01368, M/361762/01/2/OCR. Unpublished study prepared by Eurofins – GAB GmbH. 130 p.**

Field Test; conducted in Spain

Dates; April 22, 2008 to August 24, 2008

The objective of this study was to evaluate the residues of clothianidin and imidacloprid, and their metabolites, in sweet pepper plants and flowers following a seed treatment (56.25% clothianidin + 18.75% imidacloprid). The experimental design consisted of a control group (untreated seeds) and a treatment group (treated seeds). All plants were initially grown under greenhouse conditions and were later transplanted into the field. Seeds within the treatment group were treated at a rate of 0.50 mg clothianidin and 0.17 mg imidacloprid per seed. To determine residue levels, samples of young plants were taken at time of transfer from greenhouse to field and from flowers twice per week post-transfer. The limit of detection was 0.0003 mg/kg.

Results-



**Table 2. Residue Levels; Sweet Pepper**

Specimen	Residue Type	Residue Level
<b>Treatment Group</b>		
Young Plants	Clothianidin	0.233 to 0.321 mg/kg
	Clothianidin Metabolites	0.014 to 0.059 mg/kg
	Imidacloprid	0.333 to 0.353 mg/kg
	Imidacloprid Metabolites	0.012 to 0.064 mg/kg
Flowers	Clothianidin	≥0.0029 mg/kg
	Clothianidin Metabolites	none
	Imidacloprid	≥0.0024 mg/kg
	Imidacloprid Metabolites	none
<b>Control Group</b>		
Young Plants	Clothianidin	≥0.002 mg/kg <sup>1</sup>
	Clothianidin Metabolites	none
	Imidacloprid	0.002 to 0.003 mg/kg <sup>1</sup>
	Imidacloprid Metabolites	none
Flowers	Clothianidin	≥0.0036 mg/kg <sup>1</sup>
	Clothianidin Metabolites	none
	Imidacloprid	none
	Imidacloprid Metabolites	none

<sup>1</sup> residue in control plants is a result of routine use of neonicotinoids in greenhouse and field environments

Low levels of clothianidin and imidacloprid were detected in both young plants and flowers grown from pepper seeds treated with a clothianidin/imidacloprid combo product.

**47961202. Bocksch, S. (2010) Determination of Residues of Clothianidin and Imidacloprid and their Metabolites in Melon following an Application of Clothianidin & Imidacloprid WS 56.25 + 18.75 as Seed Treatment: Final Report. Project Number: M/361798/01/1, S08/01369, M/361798/01/2/OCR. Unpublished study prepared by Eurofins- GAB GmbH. 196 p.**

Field Test; conducted in Spain

Dates; April 22, 2008 to August 25, 2008

The objective of this study was to evaluate the residues of clothianidin and imidacloprid, and their metabolites, in melon plants and flowers following a seed treatment (56.25% clothianidin + 18.75% imidacloprid). The experimental design consisted of a control group (untreated seeds) and a treatment group (treated seeds). All plants were initially grown under greenhouse conditions and were later transplanted into the field. Seeds within the treatment group were treated at a rate of 1.0 mg clothianidin and 0.33 mg imidacloprid per seed. To determine residue levels, samples of young plants were taken at time of transfer from greenhouse to field and from flowers multiple times post-transfer. The limit of detection was 0.0003 mg/kg.



## Results-

**Table 3. Residue Levels; Melon**

Specimen	Residue Type	Residue Level
<b>Treatment Group</b>		
Young Plants	Clothianidin	0.93 to 11.0 mg/kg
	Clothianidin Metabolites	0.05 to 0.5 mg/kg
	Imidacloprid	0.46 to 2.6 mg/kg
	Imidacloprid Metabolites	0.02 to 0.16 mg/kg
Flowers	Clothianidin	≥0.0030 mg/kg
	Clothianidin Metabolites	none
	Imidacloprid	≥0.0095 mg/kg
	Imidacloprid Metabolites	0.0010 mg/kg
<b>Control Group</b>		
Young Plants	Clothianidin	0.0011 to 0.0032 mg/kg <sup>1</sup>
	Clothianidin Metabolites	none
	Imidacloprid	≥0.0015 mg/kg <sup>1</sup>
	Imidacloprid Metabolites	none
Flowers	Clothianidin	≥0.0025 mg/kg <sup>1</sup>
	Clothianidin Metabolites	none
	Imidacloprid	≥0.0026 mg/kg <sup>1</sup>
	Imidacloprid Metabolites	none

<sup>1</sup> residue in control plants is a result of routine use of neonicotinoids in greenhouse and field environments

Low levels of clothianidin and imidacloprid were detected in both young plants and flowers grown from melon seeds treated with a clothianidin/imidacloprid combo product.

## CONCLUSIONS:

Residues of clothianidin and imidacloprid were much lower in flowers as compared to young plants grown from seed treated with 56.25% clothianidin and 18.75% imidacloprid.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

July 30, 2009

MEMORANDUM

Subject:      Name of Pesticide Product:      Sepresto 75 WS  
                 EPA File Symbol:                   264-RNIR  
                 DP Barcode:                        366695  
                 PC Code:                        044309      Clothianidin  
   129099      Imidacloprid

From:          Breann Hanson, Biologist *BHanson*  
                 Alternative Risk Integration and Assessment (ARIA) Team  
                 Risk Integration, Minor Use, Emergency Response Branch (RIMUERB)  
                 Registration Division (RD; 7505P)

Through:      John Redden, Team Leader – Toxicology  
                 ARIA Team/RIMUERB *JR*  
                 RD; 7505P

To:             Kable Davis, PM Team 01  
                 Insecticide Branch  
                 RD; 7505P

And:           Wendy Bruce, Senior Evaluation Officer  
                 Toxicology Evaluation Section I  
                 Health Evaluation Directorate  
                 Pest Management Regulatory Agency (PMRA)

Applicant:    Bayer CropScience  
                 P.O. Box 12014, 2 TW Alexander Drive  
                 Research Triangle Park, NC 27709



FORMULATION FROM LABEL:

<u>Active Ingredients:</u>			<u>% by wt.</u>
044309	Clothianidin	CAS No. 210880-92-5	56.25
129099	Imidacloprid	CAS No. 138261-41-3	18.75
<u>Other Ingredients:</u>			<u>25.00</u>
			Total: 100.00

**ACTION REQUESTED:** The Product Manager requests: "...Please review the PMRA's primary acute toxicity review for Sepresto (264-RNIR). The reviews were emailed to John Redden on 4/9/2009. I can also forward you the email if necessary. I also included copies of the proposed label and csf...."

**BACKGROUND:** Bayer CropScience submitted a six pack of acute toxicity studies in support of registration for Sepresto 75 WS, EPA File Symbol: 264-RNIR, to Canada's PMRA, the lead agency for this joint review action. EPA has been tasked to conduct a secondary review of PMRA's acute toxicity reviews for concurrence. The studies were originally reviewed by Wendy Bruce (PMRA, Reviewer # 195) and sent to EPA. The individual studies have not been reviewed EPA; therefore, no MRIDs have been assigned.

**RECOMMENDATIONS:** The acute toxicity profile for Sepresto 75 WS, EPA File Symbol: 264-RNIR, based on PMRA's review, is:

Acute oral toxicity	III	Acceptable
Acute dermal toxicity	III	Acceptable
Acute inhalation toxicity	IV	Acceptable
Primary eye irritation	III	Acceptable
Primary skin irritation	IV	Acceptable
Dermal sensitization	Negative	Acceptable

The following are some issues/inconsistencies and comments that ARIA has with the submitted PMRA reviews:

**General comments:**

- There are minor grammatical and formatting errors throughout each review (e.g. missing periods, paragraph spacing, etc.).

**Acute Oral Toxicity (OPPTS 870.1100; OECD 425):**

- No comments. EPA is in agreement with the conclusions reached by PMRA. The



product may be classified as EPA Toxicity Category III for acute oral toxicity.

**Acute Dermal Toxicity (OPPTS 870.1200; OECD 402):**

- No comments. EPA is in agreement with the conclusions reached by PMRA. The product may be classified as EPA Toxicity Category III for acute dermal toxicity.

**Acute Inhalation Toxicity (OPPTS 870.1300; OECD 403):**

- No comments. EPA is in agreement with the conclusions reached by PMRA. The product may be classified as EPA Toxicity Category IV for acute inhalation toxicity.

**Primary Eye Irritation (OPPTS 870.2400; OECD 405):**

- No comments. EPA is in agreement with the conclusions reached by PMRA. The product may be classified as EPA Toxicity Category III for primary eye irritation.

**Primary Dermal Irritation (OPPTS 870.2500; OECD 404):**

- No comments. EPA is in agreement with the conclusions reached by PMRA. The product may be classified as EPA Toxicity Category III for primary dermal irritation.

**Dermal Sensitization (OPPTS 870.2600; OECD 406):**

- In the PMRA review, the reviewer noted that;

The positive control studies referenced in the report were not originally provided with the submission and were subsequently requested by the reviewer. In addition, the company was asked to provide the rationale for only testing up to a concentration of 50%, even though no dermal irritation was noted in the study, and also to justify the choice of vehicle (Pluronic PE 9200/0.9% NaCl solution 1% v/v) for the study.

It is the reviewer's conclusion that the company did not provide an adequate rationale for the use of Pluronic PE 9200/0.9% NaCl solution 1% v/v as the vehicle in this study. Bayer provided copies of two laboratory validation studies citing this vehicle as a suitable choice for use with water soluble materials in the LLNA [Local Lymph Node Assay] assay, however it is noted that the test material (clothianidin + imidacloprid WS 75 (56.25 + 18.75) W) is not an aqueous solution, but rather a solid powder, and as such the use of acetone/olive oil (4:1) is the preferred vehicle of choice.

In addition, the company did not provide an adequate rationale for only testing up to a concentration of 50%. Preliminary studies should have



been conducted in order to elucidate the maximum concentration of test substance that could have been utilized without compromising solubility.

However, the test material is comprised primary (approximately 78%) of the two active ingredients (clothianidin and imidacloprid), neither of which are considered to be dermal sensitizers, and in addition, none of the other components of the formulation are known sensitizers. Therefore, based on the weight-of-evidence, it is the reviewer's conclusion that the test substance is unlikely to be a dermal sensitizer.

- According to OPPTS 870.2600 Guidelines, a "positive control is added to each assay to provide an indication of appropriate assay performance". No positive control was conducted concurrently with this study, though a previous "reliability test" is referenced in the study report (Bayer HealthCare, Report No. PH-34923, 5/16/2007), conducted with alpha-hexylcinnamaldehyde in Pluronic/NaCl as the vehicle. The study shows that the testing facility can produce reliable results using a known sensitizer with Pluronic/NaCl as the vehicle.
- EPA has previously accepted LLNA studies performed with Pluronic/NaCl solutions as a vehicle.
- EPA concurs with PMRA that the company did not provide an adequate rationale (letter from Bayer CropScience to Wendy Bruce (PMRA), dated 3/17/2009) for only testing up to a concentration of 50%, especially when an earlier acute dermal toxicity study, noted above, performed at a limit dose of 2,000 mg/kg/bw did not result in any treatment related clinical signs of toxicity. Preliminary studies should have been conducted to determine the maximum concentration of test substance that could have been used without compromising solubility.
- EPA concurs with PMRA's rationale of the "weight-of-evidence" to conclude that the test substance is unlikely to be a dermal sensitizer. The product may be classified as a non-sensitizer.



**LABELING:** Based on the toxicity profile above, the following are the precautionary and first aid statements for this product as obtained from the Label Review System.

**PRODUCT ID #:** 000264-01081

**PRODUCT NAME:** Sepresto 75 WS

**PRECAUTIONARY STATEMENTS**

**SIGNAL WORD:** CAUTION

**Hazards to Humans and Domestic Animals:** Harmful if absorbed through skin or if swallowed. Causes moderate eye irritation. Avoid contact with skin, eyes or clothing. Wear long-sleeved shirt and long pants, socks, shoes, and chemical-resistant gloves.

**USER SAFETY RECOMMENDATIONS:** Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilette. Remove and wash contaminated clothing before reuse.

**First Aid:**

If on skin:

- Take off contaminated clothing.
- Rinse skin immediately with plenty of water for 15-20 minutes.
- Call a poison control center or doctor for treatment advice.

If swallowed:

- Call a poison control center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to by a poison control center or doctor.
- Do not give anything to an unconscious person.

If in eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after the first 5 minutes, then continue rinsing.
- Call a poison control center or doctor for treatment advice.

Have the product container or label with you when calling a poison control center or doctor or going for treatment. You may also contact 1-800-xxx-xxxx for emergency medical treatment information.



**DATE:** September 15, 2009

**SUBJECT:** Secondary Review of PMRA's Product Chemistry Review of End-Use Product, Sepresto 75 WS.

**FROM:** Debra Rate *Debra H. Rate*  
Alternative Risk Integration and Assessment (ARIA) Team  
Risk Integration, Minor Use and Emergency Response Branch (RIMUERB)  
Registration Division (RD; 7505P)

**THROUGH:** Shyam Mathur, Team Leader  
Product Chemistry  
Technical Review Branch (TRB) / RD (7505P)

*S. Bonaparte*  
*9/16/09*

**TO:** RM 01 Venus Eagle / Kable Davis  
Insecticide/ Rodenticide Branch / RD (7505P)

DP BARCODE: D365268  
EPA REG. NO.: 264-RNIR  
PRODUCT: Sepresto 75 WS  
PCC : 044309 (clothianidin)  
129099 (imidacloprid)  
REGISTRANT: Bayer CropScience  
USE: Insecticide

**INTRODUCTION:**

The registrant, Bayer CropScience, has submitted an application for a new registration for Sepresto 75WS, a multiple active ingredient (MAI) product. The registrant has submitted a CSF for basic formulation (dated 31/AUG/2009) and supporting product chemistry data under MRID No. 47483001. ARIA has been asked to perform a secondary review of the PMRA report and determine if the data submitted to PMRA and the Agency will support its registration.

**SUMMARY OF FINDINGS:**

1. The proposed end-use product contains the two AIs, clothianidin (EPA Reg. No. [REDACTED]) and imidacloprid (EPA Reg. No. [REDACTED]) with nominal concentrations of each AI at 18.75% and 56.25%, respectively.
2. The proposed confidential statement of formulation (CSF) for basic formulation (dated 31/AUG/2009) is filled out correctly and completely. The nominal concentrations of both active ingredients concur with the product label claim nominal concentrations. The CSF is in compliance with PR Notice 91-2. All of the inert ingredients present in the formulation have been approved by the Agency (IIAB) for application to growing crops (40CFR§180.920). The certified limits proposed for the

\*Product ingredient source information may be entitled to confidential treatment\*



active ingredient and for the inert ingredients are in compliance with the standard certified limit table set-forth in 40CFR§158.350(b)(2) or slightly wider limits have been accepted based on submitted justification.

2. The product chemistry data submitted corresponding to guideline 830.1600 (description of materials use to produce the product) satisfy the data requirements of 40CFR§158.320. The registrant has provided the MSDS for all the starting materials used to produce the end-use product [MRID No. 47483001].
3. The product chemistry data submitted corresponding to guideline reference 830.1650 (description of formulation process) satisfy the data requirements for 40CFR§158.335. The end-product is produced through a simple batch process [MRID No. 47483001].
4. The product chemistry data submitted corresponding to guideline reference 830.1670 (Discussion on the formation of impurities) satisfy the data requirements for 40CFR§158.340. The registrant has reported that no reactions are expected between the AI, the impurities, the formulation ingredients [MRID No. 47483001].
5. The data submitted corresponding to the guideline reference 830.1800 (Enforcement Analytical method) satisfy the data requirements of 40CFR§158.355. The HPLC/UV (270 nm) method was used to determine the active ingredient content of both AIs [MRID No. 47483001].
6. The product chemistry data submitted corresponding to guideline reference 830 Series Subgroup B (physical/chemical properties) for the proposed end-use product, Sepresto 75WS, satisfy the data requirements of 40CFR§158.310(e), with the exception of the one year storage stability (830.6320) and corrosion characteristics (830.6320) studies. The registrant reported that the storage stability and corrosion characteristics studies have been initiated and will be submitted to the Agency upon completion [MRID No. 47483001].
7. The ingredient and storage / disposal statements on the proposed label meet label requirements from a product chemistry point of view.

## CONCLUSIONS

ARIA has reviewed the product chemistry data submitted for 830 series Subgroup A & Subgroup B for the end-use product, Sepresto 75WS and has concluded that:

1. The CSF for basic formulation (dated 31/AUG/2009) is acceptable.
2. The product chemistry data submitted corresponding to guidelines 830 series subgroup A are acceptable.



3. The product chemistry data submitted corresponding to guidelines 830 series subgroup B are acceptable, except for the one year storage stability (830.6317) and corrosion characteristics (830.6320).

4. The registrant must submit the results of one year storage stability (830.6317) and corrosion characteristics (830.6320) to the Agency on completion. It is recommended that the observations must be made at 0, 3, 6, 9, & 12 month intervals. The results must be submitted in a hard copy and an electronic format is also requested.

**Note: The PMRA report is attached below. The Agency agrees with PMRA's decisions as they reflect U.S. EPA requirements. Highlighted in red on pages 10 and 11 of this review are edits or what the reviewer believes to be typos.**



Chemistry data review for the registration of a manufacturing concentrate (MA) or an end-use product (EP).

**Product Chemistry Data Requirements**

**Product Name:** Sepresto 75 WS

**Submission Number / DP Bar Code:** 2008-3575

**Registration Number:** Not yet assigned

**Source Code(s) / PC Code:** COD-BCQ-1, TKS-1 and BBA-1 for Clothianidin  
IMI-BBA-5 for Imidacloprid

**Applicant's / Registrant's Name and Address:** Bayer CropScience Inc.  
3131 114th Ave. S.E., Suite 100  
Calgary, Alberta  
Canada, T2Z 3X2

**Formulating Plant's Name and Address:** Bayer CropScience  
P.O. Box 12014,  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709  
USA

**TGAI(s) in EP:** Clothianidin Technical Insecticide, PCP # 27445 containing chlothianidin at 97.5% nominal and,  
Bay NTN 33893 Technical Insecticide, PCP # 24468, containing imidacloprid at 98% nominal

**Guarantee:** On the Statement of Product Specification Form (SPSF) dated 2008-08-01:  
Clothianidin ..... 56.25 % (Limits: 54.6-57.9 %)  
Imidacloprid..... 18.75 % (Limits: 18.2-19.3 %)

On the proposed label:  
Clothianidin ..... 56.25 %  
Imidacloprid..... 18.75 %

**INTRODUCTION:**

The purpose of this category B2.6-S-N-EP C8.1 submission is to register a new end-use product containing the active ingredients clothianidin and imidacloprid under the second-entry joint review by Canada and USA. In support of this application for registration, Bayer has submitted a draft label, Part 3-product chemistry data and a Statement of Product Specification Form dated 2008-08-01.

**SUMMARY OF FINDINGS:**

Sepresto 75 WS is guaranteed to contain the active ingredients Clothianidin and Imidacloprid at nominal concentrations of 56.25 % (Limits: 54.6-57.9 %) and 18.75 % (Limits: 18.2-19.3 %) respectively.



A fully validated method is provided for the simultaneous determination of the active ingredients in the EP. The method is found to be suitable for use as an enforcement analytical method.

Chemical and physical properties applicable to the product have been provided. The storage stability data and corrosion characteristic studies have not been provided as they are currently in progress.

Based on the formulating process used, impurities and formulates of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, are not expected to be present in the product or carried through from the TGA1.

CBI: Formulates and impurities of human health or environmental concern as identified in the PMRA formulates database, Section 2.13.4 of Dir98-04 and Appendix II of Dir99-03 (excluding those identified in the Canada Gazette) are not expected to be present in the product or carried through from the TGA1. The product does not contain any PMRA List 1 or 2 formulates.

The following deficiencies remain to be addressed.

**DACO:** 3.2.2  
**Title:** Statement of Product Specification Form (SPSF)  
**Deficiency:**  
1. In row 2, box 6, page 1 the PCP # is listed instead of the purity.  
2. In row 2, box 3, page 1 the chemical name of imidacloprid does not present its isomeric configuration.  
3. In rows 2 and 3, page 2, the CAS #s are listed in respective box 15.

**Required Clarifications:** The applicant must provide a revised SPSF on which:  
1. The PCP # is replaced with the purity value.  
2. The chemical name is changed to (E)-1-(6-chloro-3-pyridylmethyl)-N-nitroimidazolidin-2-ylideneamine.  
3. The CAS numbers for these two formulates are moved to the appropriate box 7.

**DACO:** 3.5.10/3.514  
**Title:** Storage Stability/ Corrosion Characteristics  
**Deficiency:** The results of a one year storage stability and corrosion characteristic studies were not submitted.  
**Required Data:** The applicant must submit the results of the long term storage stability and corrosion characteristic of the product upon completion of the studies. In the meantime, the anticipated completion and submission dates of the studies must be provided.

#### CONCLUSIONS:

CES review status: Level C -Started

#### Good Laboratory Practices Compliance Statement:

The studies contained within this report were conducted in accordance with the Good Laboratory Practice Standards as specified in 40 CFR 160.



yes ☒ no ☐ not stated / applicable ☐

#### Label Review

1. The active ingredient statement (chemical identity, nominal concentration) is consistent with the CSF / SPSF.

yes ☒ no ☐

2. The formulation contains one of the following:

10% or more of a petroleum distillate:	yes <input type="checkbox"/>	no <input checked="" type="checkbox"/>
1% or more of methyl alcohol:	yes <input type="checkbox"/>	no <input checked="" type="checkbox"/>
sodium nitrite at any level:	yes <input type="checkbox"/>	no <input checked="" type="checkbox"/>
a toxic List 1 inert at any level:	yes <input type="checkbox"/>	no <input checked="" type="checkbox"/>
arsenic in any form:	yes <input type="checkbox"/>	no <input checked="" type="checkbox"/>

3. If yes to any of the above, does the inert ingredients statement contain a footnote indicating this?

yes ☐ no ☐ not applicable ☒

4. The appropriate physical and chemical hazards statement regarding flammability or explosive characteristics of the product are given on the label:

yes ☐ no ☐ not applicable ☒

5. The storage and disposal instructions for the pesticide and container are in compliance with PMRA Registration Handbook / PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses:

yes ☐ no ☐ see DACO 8.4 in EAD review summary ☐

Refer to the annotated label in the workbook for comments on the storage and disposal statements for this label

#### Chemical and Physical Properties: See Table 1.

##### Reference:

- PMRA 1636638, 2008, Product chemistry of Sepresto 75WS, BR 2645, MRID: 47483001, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 2.1,II, (Data # 1)
- PMRA 1640384, Statement of Product Specification Form dated 2008-08-01 (Data # 1)
- PMRA 1640819, Background Information and Review team (Data # 1)

Table 1. Chemical & Physical Properties				
DACO # / GLN	Title	MRID / Ref. #	Status <sup>1</sup>	Result <sup>2</sup> or Deficiency
3.5.1 / 830.6302	Colour	Ref. 1	A	Grey
3.5.2 / 830.6303	Physical State	Ref. 1	A	Powder



Table 1. Chemical & Physical Properties				
DACO # / GLN	Title	MRID / Ref. #	Status <sup>1</sup>	Result <sup>2</sup> or Deficiency
3.5.3 / 830.6304	Odour	Ref. 1	A	Not provided
3.5.4	Formulation Type	Ref. 1	A	Wettable powder (WP)
3.5.5	Container Material and Description	Ref. 3	A	2 to 10 kg paper
3.5.6 / 830.7300	Density	Ref. 1 Ref. 1 Ref. 2	A	Bulk density is 0.24g/mL Tapped density is 0.31 g/mL 0.24-0.48 g/mL
3.5.7 / 830.7000	pH	Ref. 1 Ref. 2	A	8.1 8-10 (2% water)
3.5.8 / 830.6314	Oxidizing or Reducing Action	Ref. 1	A	Sepresto ® 75WS does not contain any ingredient (technical or inert) which is considered to be an oxidizing or reducing agent.
3.5.9 / 830.7100	Viscosity	Ref. 1	N/A	The product is a solid.
3.5.10 / 830.6317	Storage Stability Data	Ref. 1	N	A one year storage stability study is in progress and will be submitted when completed.
3.5.11 / 830.6315	Flammability	Ref. 1	N/A	Sepresto ® 75WS does not contain a combustible liquid.
3.5.12 / 830.6316	Explosibility	Ref. 1	N/A	No impact explosive characteristics are expected on the basis of the chemical nature of the formulation ingredients.
3.5.13 / 830.6319	Miscibility	Ref. 1	N/A	The end- use product is not intended for dilution with petroleum solvents.
3.5.14 / 830.6320	Corrosion Characteristics	Ref. 1	N	A one year corrosion study is being conducted in conjunction with the one year storage stability study and will be submitted when available.
3.5.15 / 830.6321	Dielectric Breakdown Voltage	Ref. 1	N/A	The end- use product is not intended for use around electrical equipment.
<sup>1</sup> A = Acceptable; N = Unacceptable (see Deficiency); N/A = Not applicable. <sup>2</sup> For example, "brown" for 830.6302; "1.021" for 830.7300.				

Data Submitted: See Table 2.



Table 2. Data Submitted for Sepresto 75 WS EP				
DACD # / GLN	Title	MRID / Report #	Status <sup>1</sup>	Details and/or Deficiency <sup>2</sup>
3.2.1 / 830.1600	Description of Starting Material		A	
3.2.2 / 830.1620 830.1650	Production / Formulation Process		A	
3.2.3 / 830.1670	Discussion of Impurities		A	
3.3.2 / 830.1550	Control Product Specification Form / Confidential Statement of Formula		N	Minor deficiencies.
3.3.1 / 830.1750	Certification of Limits		A	
830.17	Preliminary Analysis		N/A	<i>For EP containing non-registered TGA1 or for EP which is an INP only.</i>
3.4.1 / 830.1800	Enforcement Analytical Method		A	
<sup>1</sup> A - Acceptable; N - Unacceptable (see Deficiency); N/A - Not applicable. <sup>2</sup> Refer to CBI Appendix A for details				

ATTACHMENT: CONFIDENTIAL APPENDIX A



**CONFIDENTIAL APPENDIX A: MANUFACTURING, COMPOSITION AND FORMULANT INFORMATION.**

**Formulation Process**

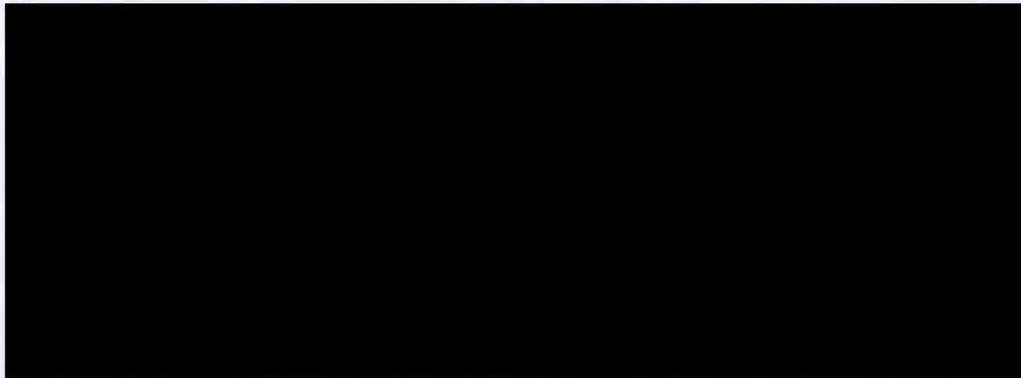
Reference: PMRA 1636638, 2008, Product chemistry of Sepresto 75WS, BR 2645, MRID: 47483001, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 2.1,II, (Data # 1)

**3.2.1 / 830.1600 Description of Starting Materials**

A full description of the starting materials including specifications and MSDSs has been provided.

**3.2.2 / 830.1650 Description of the Formulation Process**

Sopresto 75 WS is a wettable powder formulation. The following is the recommended formulating procedure.



**3.2.3 / 830.1670 Discussion of the Formation of Impurities/Impurities of Toxicological Concern**

No impurities other than those already present in the technical products are expected in the product as a result of formulation process.

**Conclusion:** The starting materials and the formulation process are satisfactorily described.

**3.3.1 / 830.1750 Certification of Limits**

The nominal concentration (NC) of the active ingredient and the lower and upper certified limits (LCL & UCL) are shown in Table 1.

Table 1. Certification of Limits			
Active Ingredient	NC (w %)	LCL (w %)	UCL (w %)
Clothianidin	56.25	54.6	57.9
Imidacloprid	18.75	18.2	19.3

**Conclusion:**



1. The calculated NC, based on the pure active ingredient (PAI), is identical to that on the label.

yes [ x ]

no [ ]

2. The certified limits are within the standard limits as per DACO 3.3.1/40CFR§158.175 or are adequately explained if different.

yes [ x ]

no [ ]

not applicable [ ]

### 3.4.1 / 830.1800 Enforcement Analytical Method

Reference: PMRA 1636638, 2008, Product chemistry of Sepresto 75WS, BR 2645, MRID: 47483001, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 2.1,II, (Data # 1)

The following table presents the details of the method used.

Table 2. Details of the analytical method used to determine clothianidin and imidacloprid in Sepresto75 WS	
Method ID	Bayer Analytical Method: AM009607MF1- Determination of Clothianidin and Imidacloprid in Formulations Bayer Validation Report No.: VB2-AM009607MF1; Validation of HPLC-method AM009607MF1- Determination of clothianidin and imidacloprid in formulations clothianidin+imidacloprid WS 75 (562.5+187.5 g/kg)
Sample preparation	Accurately weigh an amount of the homogeneous sample containing approximately 35 mg Clothianidin and dissolve in approximately 50 mL acetonitrile. <del>To dissolve the substance, place flask in an ultrasonic bath for 15 min. Wait until the temperature has stabilized and fill to the mark with water and mix.</del> Note: These weights are valid for formulation with the active concentration of approximately 28.6% clothianidin and 19.1% imidacloprid. For formulations with a different concentration range of the active ingredient, the weight of the reference substance must be adjusted to the altered concentration range.
Instrument	HPLC
Detector	UV at 270 nm
Column	Alltima C18, <del>50</del> mm x 4.6 mm, 3µ
Mobile phase	1 L water + 1 ml acetic acid /acetonitrile 82/18 (v/v)
Oven temperature	50°C
Quantitation	External standard by comparing peak areas with those of the reference standards
Retention time	Clothianidin 1.35 min. Imidacloprid 1.60 min.
Total run time	3 min.
Chromatograms	Chromatograms of standard solutions and sample solution were provided and showed well resolved peaks with no interferences observed.

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The validation data are shown in Table 3.



**Table 3. Validation data for clothianidin and imidacloprid in Sepresto75 WS**

Method ID	Method type	Linearity (mg/100 mL)	Recovery (%)	RSD (%)	MA <sup>1</sup>
Clothianidin	HPLC/UV	21.0 to 52.0 mg/100mL $r^2$ : 0.99991	99.26	0.68	A
Imidacloprid	HPLC/UV	13.0 to 36.9 mg/100 mL $r^2$ : 0.99999	101.00	1.58	A
<sup>1</sup> MA = Method acceptability; A = acceptable; N = not acceptable (see deficiency).					

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**Conclusion:** An analytical method was provided for the determination of the active. The method was assessed to be selective, precise and accurate for use as an enforcement analytical method.

#### Specific Data Reviewed by PMRA

#### 3.3 Specifications:

Reference: PMRA 1640384, Statement of Product Specification Form dated 2008-08-01(Data # 1)

#### 3.3.2 / 830.1550 Statement of Product Specification Form / Confidential Statement of Formula



### 3.4.2 Impurities of human health or environmental concern

**Reference:** PMRA 1636638, 2008, Product chemistry of Sepresto 75WS, BR 2645, MRID: 47483001, DACO: 3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 2.1,II, (Data # 1)

Based on the formulating process used, impurities and formulants of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 139, No. 24, SI/2005-114 (2005-11-30), including TSMP Track 1 substances and allergens known to cause anaphylactic-type reactions, are not expected to be present in the product or carried through from the TGA1.

#### Review History (for PMRA data tracking purpose only).

##### Data Submission and Review History:

Table 5. Correspondence Dates, Data # and Content for Sepresto 75 WS			
Date Received	Data #	Content Summary	Reviewer Officer #
Sep-25-2008	1	Label, a Statement of Product Specification Form and Part 3- Product Chemistry.	336

**Summary written by:** Officer # 336  
**Date written:** January 27, 2009  
**Peer-reviewed by:** Officer # 366  
**Date peer-reviewed:** March 26, 2009  
**Update written by:** Officer # ... on date  
**Peer-reviewed by:** Officer # ... on date

**Review Retrievability:** The Part 3 DER is saved in the PMRA Database Workbook under Submission 2008-3575, CES Review Stream, DocID 3.0, PMRA 1706317

#### Review signed off:

\_\_\_\_\_  
Jesse Ng  
Section Head, Chemistry Evaluation Section (CES)  
CLSROD  
Date: \_\_\_\_\_

#### References:

1636638 2008, Product chemistry of Sepresto 75WS, BR 2645, MRID: 47483001, DACO:  
3.2.1,3.2.2,3.2.3,3.3.1,3.3.2,3.4.1,3.4.2,3.5.1,3.5.10,3.5.14,3.5.2,3.5.3,3.5.6,3.5.7,IIIA 1.4.1,IIIA 1.4.2,IIIA 1.4.3.1,IIIA 1.4.3.3,IIIA 1.4.4,IIIA 1.4.5.1,IIIA 1.4.5.2,IIIA 2.1,II  
1706317 DACO: 3.0\_DOC





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PC Code: 044309  
Date: October 21, 2009  
DP Barcode: 370427

**MEMORANDUM**

**SUBJECT:** Clothianidin Registration of New Products and New Uses of Sepresto 75WS and PROCEED™ OPTIMUM: Addendum to Address Mitigation of Bee Hazard

**FROM:** Allen W. Vaughan, Entomologist *Allen W. Vaughan*  
Environmental Risk Branch V *10/29/09*  
Environmental Fate and Effects Division (7507P)

**THROUGH:** Mah T. Shamim, Branch Chief *Mah T. Shamim*  
Environmental Risk Branch V *10/29/09*  
Environmental Fate and Effects Division (7507P)

**TO:** Kable Davis, Risk Manager Reviewer  
Venus Eagle, Risk Manager  
Meredith Laws, Branch Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

EFED recently conducted a risk assessment for a number of proposed new agricultural uses for clothianidin products, under DP355370. That assessment characterized the potential hazard to foraging pollinators from uses of clothianidin on flowering plants. This addendum addresses in more detail the potential hazards to pollinators by identifying hazards for each crop and specific application method, and suggests measures to mitigate hazards for foliar uses of clothianidin. Because of the extreme persistence of clothianidin in soil environments (half-life = 148 to 1,155 days) and the potential for translocation of this systemic pesticide to pollen and nectar, EFED does not believe that precautionary bee labeling language will effectively mitigate hazards from soil treatment or seed application of clothianidin to cucurbits and fruiting vegetables. In addition, succeeding berry crops or rotational crops that are planted following soil treatment or seed application have the potential to expose bees to residues of clothianidin in the soil.



### **Background:**

Clothianidin is a systemic nicotinoid insecticide that may be applied via foliar, soil, or seed application. Due to its systemic properties, it may be present in/on plant tissues following any method of application. Clothianidin is also highly toxic to bees on both an acute contact and oral exposure basis ( $LD_{50} = 0.0439$  and  $0.0037$  ug a.i./bee, respectively), and is extremely persistent in soil environments. Thus, there is a concern from the proposed soil and seed treatment uses as well as proposed foliar application uses.

The new uses involved in this request are leafy vegetables, Brassica leafy vegetables, fruiting vegetables, cucurbits, and low-growing berries, except strawberries (both foliar and soil); tree nuts, figs, pomegranates, cotton, peaches, and soybeans (foliar only).

Attached is a table developed by David Brassard of BEAD which provides detailed information regarding the potential for bee exposure from the proposed new uses. The information in the attached table regarding relative risk may be summarized as follows:

**Low potential for exposure to bees:** Brassica leafy vegetables and leafy vegetables (crops are harvested prior to bloom); figs (bees are unlikely to visit this crop).

**Moderate /high potential for exposure, but risk may be mitigated for foliar uses if label precautions (which prohibit application prior to and during bloom) are followed:** foliar application to low-growing berries, cotton, cucurbits, fruiting vegetables, peaches, pomegranates, soybeans, and tree nuts.

**Potential for exposure in pollen/nectar following soil treatment:** cucurbits, fruiting vegetables, and berries. Because clothianidin is extremely persistent in soil and is a systemic pesticide, there is a potential for this chemical to be translocated from the soil up through the plant into pollen and nectar. Translocation of clothianidin from the soil to the pollen and nectar of canola has been demonstrated in field studies conducted with clothianidin-treated seeds. In addition, studies conducted by Bonmatin 2005 have found that the nitroguanidine neonicotinoid, imidacloprid, which is in the same chemical class as clothianidin, translocates from the soil to the pollen of corn and sunflower plants.<sup>1</sup> Thus, there is a risk concern for pollinators foraging on blooming plants following seed or soil treatment. In addition because clothianidin is persistent in soil, residues may remain in the soil and be translocated into the nectar and pollen of succeeding and rotational crops. The potential for exposure of pollinators to clothianidin via this route is significant, but mitigation measures have not been developed to protect bees from exposure to soil-applied systemic pesticides.

<sup>1</sup> Bonmatin, J.M., P.A. Marchand, R. Charvet, I. Moineau, E.R. Bengsh, and M.E. Colin. 2005. Quantification of Imidacloprid Uptake in Maize Crops. *J. Agric. Food Chem.* 53: 5336-5341; Bonmatin, J.M., I. Moineau, R. Charvet, M.E. Colin, C. Fleche, E.R. Bengsch. 2005. Behavior of Imidacloprid in Fields. Toxicity for Honey Bees. In *Environmental Chemistry: Green Chemistry and Pollutants in Ecosystems*, ed. E. Lichtfouse, J. Schwarzbauer, D. Robert. New York: Springer.



### Potential for Honeybee Exposure to Clothianidin by Crop and Application Method

Crop/Crop Group	Pests	application method	Likelihood of application during bloom <sup>1</sup>	Potential for honeybee visitation <sup>2</sup>
berries (low-growing)	Cranberry weevil, flea beetles,	Foliar post bloom	Low	High
		Soil post bloom	None <sup>3</sup>	High
Brassica leafy vegetables	Aphids, flea beetles, leafhoppers, whiteflies	Foliar	Low	Low
		Soil	None	Low
Cotton	Aphids, Lygus bugs, whiteflies	foliar	High	Moderate
Cucurbits	Aphids, flea beetles, leafhoppers, whiteflies	Foliar	High	High
		Soil	Medium-High <sup>4</sup>	High
Figs	Dried fruit beetle, fig scale, vinegar flies	Foliar post bloom	Low	Low
Fruiting vegetables	Aphids, Colorado potato beetle, flea beetles, leafhoppers, Lygus bugs, pepper weevil, stink bugs, whiteflies	Foliar	High	Moderate
		Soil	Medium-High <sup>4</sup>	Moderate
leafy vegetables	Aphids, flea beetles, leafhoppers, whiteflies	Foliar	Low	Low
		Soil	None	Low
Peaches	Aphids, leafhoppers, plum curculio, scale, stink bugs	Foliar post bloom	Low	High
Pomegranates	Aphids, leafhoppers, sharpshooters, whiteflies	Foliar post bloom	Low	Moderate
Soybeans	Aphids, bean leaf beetle, leafhoppers, Lygus bugs, stink bugs, whiteflies	Foliar	High	Moderate
Tree Nuts	Aphids, hickory shuckworm, leafhoppers, leafhoppers mealybugs, pecan nut casebearer, scale, whiteflies	Foliar post bloom	Low	High

<sup>1</sup> Likelihood of application during bloom primarily determined by the presence of damaging pest populations during the blooming period; if growers adhere to the label restrictions against application during bloom, all of the entries in this column would be "low" except for berries, cucurbits, and fruiting vegetables.

<sup>2</sup> Potential for honeybee visitation: **high**: crop frequently pollinated by honeybees transported to the field by commercial migratory beekeepers; **moderate**: crop naturally pollinated by honeybees and other pollinator species; **low**: crop does not require pollination by honeybees to reach marketable stage

<sup>3</sup> Soil application of clothianidin to succeeding berry crops or rotational crops may pose a hazard to bees from residues that remain in the soil.

<sup>4</sup> The current label allows clothianidin to be applied to cucurbits and fruiting vegetables as a soil treatment at any time from planting through 7 days pre-harvest. Because this chemical is persistent in soil environments and systemic, any soil treatment prior to or during bloom may result in residues in pollen and nectar. Thus, there is a potential for hazard to pollinators even if the application is not made during bloom. Mitigation measures have not been developed to protect bees from this route of exposure.





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PC Code: 044309  
Date: September 15, 2009

DP Barcodes: ~~330014~~, 343422, 355370, 355371, 355372, 357017, 362361, 362362

**MEMORANDUM**

**SUBJECT:** Clothianidin Registration of New Products Sepresto 75WS and PROCEED™ OPTIMUM, for Seed Treatment; New Uses for the Chemical on Tuberous and Corm Vegetables (CSG 1C), Bulb Vegetables (Seed Treatment only) (CG 3), Leafy Greens (CG 4), Brassica (Cole) Vegetables (CG 5), Fruiting Vegetables (CG 8), Cucurbit Vegetables (CG 9), Cranberry and Low Growing Berries (Except Strawberry) (CSG 13-07H), Tree Nuts (CG 14), Cereal Grains (Except Rice, Seed Treatment Only) (CG 15), Figs, Pomegranates, Cotton, Soybeans, Peach and Potato Seed Pieces Treatment

**FROM:** José L. Meléndez, Chemist *José Luis Meléndez*  
N.E. Federoff, Wildlife Biologist *N.E. Federoff*  
Environmental Risk Branch V *09/15/09*  
Environmental Fate and Effects Division (7507P)

**THROUGH:** Mah T. Shamim, Branch Chief *Mah T. Shamim*  
Environmental Risk Branch V *9/15/09*  
Environmental Fate and Effects Division (7507P)

**TO:** Kable Davis, Risk Manager Reviewer  
Venus Eagle, Risk Manager  
Meredith Laws, Branch Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

EFED has conducted a revision of the proposed new uses for clothianidin. At this time, a new ecological risk assessment is not required because the previously issued assessments cover the new uses. The risks found in previous assessments should be similar for the new uses. The previous assessments are the following: D278110, D287186+, D335254.



**Background:**

The registrants of clothianidin, Bayer CropScience and Valent U.S.A., are applying for registration of new multiactive ingredient products for seed treatment and for several new uses of the chemical. This review covers only the active ingredient clothianidin.

The first registrant Bayer CropScience is petitioning registration of two multiactive ingredient products for seed treatment. One product is Sepresto 75WS (EPA Reg. No. 264-XXX), containing clothianidin (56.25%) and imidacloprid (18.75%). This product is for the treatment of seeds of root vegetables (CG 1), bulb vegetables (CG 3), leafy green vegetables (CSG 4A), brassica (cole) vegetables (CG 5), fruiting vegetables (CG 8), cucurbit vegetables (CG 9), cereal grains (except rice) (CG 15) and potato seed pieces. The other product is PROCEED™ OPTIMUM (EPA Reg. No. 264-XXX), containing clothianidin (1.46%), and the fungicides prothioconazole (1.46%), tebuconazole (0.29%) and methalaxil (0.59%), for the treatment of seeds of barley, wheat & triticale.

The second registrant Valent U.S.A. is petitioning new uses of clothianidin for its products Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-10170 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152) and Belay 16WSG (EPA Reg. No. 59639-153). Of these products, V-10170 5FS is for seed treatment only. The new uses involved are tuberous and corn vegetables (CSG 1C), leafy greens (CG 4), brassica (cole) vegetables (CG 5), fruiting vegetables (CG 8), cucurbit vegetables (CG 9), cranberry and low growing berries (except strawberry) (CSG 13-07H), tree nuts (CG 14), figs, pomegranates, cotton, soybeans and peach.

It is noted that there is overlap between the petitions by Bayer CropScience and Valent U.S.A. A table of the uses is included in the Appendix A. The new uses are shaded yellow and bolded, while the current uses are not shaded.

**Previous Assessments Cover Current Uses**

EFED has previously conducted various assessments of uses of clothianidin. For example, on 2/20/03, EFED conducted an assessment of the use of the chemical for canola and corn seed treatment (D278110). Later, on 11/4/05 and 9/28/05, assessments of the use of clothianidin on tobacco, turf, apples, pears, ornamentals, potatoes and grapes, and seed treatment of sorghum and cotton were conducted (D287186+ and D313414). The assessment of the treatment of sugarbeet seeds (D335254, 6/12/07), was based on a previously issued Section 18 for the same use (D326569+, 2/23/06).

Of the previously assessed uses, the one that involves the greatest exposure to aquatic organisms, is turf, with a single application at 0.4 lb a.i./A. For ornamentals in commercial and residential outdoor landscapes, a single soil application at 0.4 lb a.i./A is also allowed. Of the new uses for seed treatment, it appears that the highest application rate is for root and tuberous vegetables (represented by carrots) and potato seed pieces (application rate of approximately 0.25 lb a.i./A). The maximum seasonal application rate for the new uses, according to the labels, is specified in Sepresto 75WS. It is 0.375



lb a.i./A for root and tuberous vegetables, bulb vegetables, leafy green vegetables, brassica (cole) leafy vegetables, fruiting vegetables and cucurbit vegetables. This rate is still lower than the one for turf.

The aquatic exposure for the new uses is expected to be similar to those previously found for turf and other crops, and the risks found for aquatic organisms should be similar for the new crops. The exposure to terrestrial organisms related to the new uses should be similar to the ones for previously assessed uses, such as turf and ornamentals (maximum application rate 0.4 lb a.i./A), and for apples, pears and potatoes (for which a seasonal rate of 0.2 lb a.i./A was assessed). A listing of endangered species was not attached due to the volume of such a listing because of the multitude of crop uses.

#### ***Reported Incident***

Bayer has submitted an interim report (MRID 477987-01) on a study they are conducting in Austria. According to the report, the objective of the study was to investigate the frequency at which maize seedlings exude guttation fluid and to assess the relevance of guttation fluid to honeybees. Although not specifically mentioned in the text of the report, the study material appears to be clothianidin (based on one of the report figures). Over the two study areas, roughly 83% of the maize seedlings exuded guttation liquid. According to the report 16% of the assessment days at which guttation fluid was observed, honeybees were present when no alternative water supply was available; however, when alternative water was available, the honeybee visitation rate was 4%. Clothianidin residue levels in bees were greater than the level of quantification up to 14 days after seedling emergence; in bees without alternative water supply, honeybee mortality appeared to be correlated with clothianidin residues; however, the number of bees for which this relationship existed is uncertain. The study authors state that despite an increased bee mortality in some hives for 1 - 3 days during the survey, the overall development of the hives was not adversely affected by guttation fluid even under realistic, worst case exposure conditions.

This is an interim report and it does not contain sufficient detail or raw data with which to understand the study. The methods section does not describe the placement of colonies with and without water, nor is it possible to determine what bees were actually foraging on during the study period. It appears from the study that at least some of the bees did take advantage of the guttation liquid and that they were exposed to clothianidin. In some cases, bees exhibited behavioral effects and increased incidence of mortality that appeared to be associated with elevated clothianidin residues.

Clothianidin is a neonicotinoid insecticide that is relatively persistent in the environment; the compound is intended to be systemic in plants and the extent to which residues may be present in various plant tissues from seed treatments is uncertain. Clothianidin is highly toxic to bees on both an acute contact and oral exposure basis. A concern from the current seed treatment uses may be to beneficial insects (pollinators) that forage on crops grown from treated seed where exposure may occur through ingestion of residues in pollen and nectar as well as through guttation water produced by developing seedlings. Seed treatments are normally considered a lower exposure element to bees due to full



ground incorporation of the seeds as well as a low drift component of the application to adjacent areas where bees may forage. However, recent incidents in Europe resulting from seed treatments where appropriate stickers were not utilized, indicate that dust-off drift can also have a significant impact on pollinators foraging in the vicinity of recently seeded fields under some environmental conditions. As such, there is uncertainty regarding the extent to which seed treatments may represent a route of exposure due to the compound's systemic and persistent nature.



## Appendix A: Summary of Use Information for Clothianidin

**Table 1. Summary use information for clothianidin, including current uses (not shaded) and proposed uses (shaded gray and bolded) [from proposed labels for Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-1017 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152), Belay 16WSG (EPA Reg. No. 59639-153), Sepresto 75WS<sup>3</sup> (EPA Reg. No. 264-XXX) and PROCEED™ Optimum<sup>4</sup> (EPA Reg. No. 264-XXX)].**

PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A) <sup>12</sup>	SEASONAL APP. RATE (lb. a.i./A)	Comments
Sepresto 75WS <sup>4</sup>	Root & Tuber veg.(CG1)	NA	0.01575	0.24 <sup>5</sup>	0.375	Seed Treatment
Arena 50WDG, V-10170 2.13SC	Tuberous and corm veg (CSG 1C)	NA	NA	0.05 In furrow 0.2	0.2	
Sepresto 75WS	Potato Seed pieces	0.20	NA	0.25*	NS	Seed Treatment
Arena 50WDG, V-10170 2.13SC, Belay 16WSG	Potato	NA	NA	0.05 In furrow 0.2	0.2	
V-10170 2.13SC	Potato Seed pieces	0.14	NA	0.175*	NS	
V-1017 5FS	Potato Seed pieces	0.12	NA	0.15*	NS	Seed Treatment -- *based on seeding rate of 2000 lb/A (from this label)
Sepresto 75WS	Bulb veg. (CG 3)	NA	0.0071	0.19 <sup>6</sup>	0.375	Seed Treatment
Sepresto 75WS	Leafy Greens veg. (CG 4 or 4A)	NA	0.028	0.075 <sup>7</sup>	0.375	Seed Treatment
Arena 50WDG, V-10170 2.13SC		NA	NA	0.067 Soil-0.2	0.2	
Sepresto 75WS	Brassica (Cole) Leafy veg (CG 5)	NA	0.0416	0.11 <sup>8</sup>	0.375	Seed Treatment
Arena 50WDG, V-10170 2.13 SC		NA	NA	Foliar-0.067 Soil-0.2	0.2	
Sepresto 75WS	Fruiting veg. (CG 8)	NA	0.0174	0.001 <sup>9</sup>	0.375	Seed Treatment
Arena 50WDG, V-10170 2.13SC		NA	NA	0.067 Soil-0.2	0.2	
Sepresto 75WS,	Cucurbit veg. (CG 9)	NA	0.034	0.046 <sup>10</sup>	0.375	Seed Treatment
Arena 50WDG, V-10170 2.13SC		NA	NA	0.067 Soil-0.2	0.2	
Arena 50WDG, V-10170 2.13SC	Tree Nut (CG 14)	NA	NA	0.1	0.2	



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PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A) <sup>12</sup>	SEASONAL APP. RATE (lb. a.i./A)	Comments
Sepresto 75WS	Cereal Grain (CG 15 w/o rice) (e.g. corn, barley, sorghum, wheat)	1.13	NA	0.094 <sup>1</sup>	NA	Seed Treatment
PROCEED™ OPTIMUM <sup>5</sup>	Barley, wheat & triticale	0.11	NA	0.0090 <sup>1</sup>	NA	Seed Treatment
V-10170 5FS	Sorghum	3.1	NA	0.02 <sup>13</sup>		Seed Treatment
V-10170 5FS	Canola, Rapeseed	4.89	NA	0.05 <sup>13</sup>		Seed Treatment
V-10170 5FS	Corn (field, pop. seed & sweet corn)	NA	NA	0.1 <sup>13</sup>		Seed Treatment: 5.64 oz product/ 80,000 seed; 1.25 mg a.i./ kernel
Arena 50WDG, V-10170 2.13SC	Figs	NA	NA	0.0938	0.2	
Arena 50WDG, V-10170 2.13SC	Pomegranates	NA	NA	0.0938	0.2	
Arena 50WDG, V-10170 2.13SC	Cotton	NA	NA	0.067	0.2	Foliar applic.
V-10170 5FS	Soybeans	0.612	NA	0.02 <sup>11</sup>	NS	Seed treatment
Arena 50WDG, V-10170 2.13SC		NA	NA	0.067	0.2	
Arena 50WDG	Peach	NA	NA	0.1	0.2	
Arena 50WDG, V-10170 2.13SC	Cranberry and low growing berry, except strawberry (CSG 13-07H)	NA	NA	0.066 Soil: 0.2	0.2	
Arena 50WDG, V-10170 2.13SC, Clutch 50WDG	Grapes	NA	NA	0.1 soil 0.2	0.2	
Arena 50WDG, V-10170 2.13SC, Clutch 50WDG	Pome Fruits (various)	NA	NA	0.2	0.2	
Arena 50WDG, V-10170 2.13SC, Belay 16WSG	Tobacco	NA	NA	0.0625 soil 0.2	0.2	
Arena 50WDG, V-10170 2.13SC	Turfgrass	NA	NA	0.4	0.4	Highest individual & seasonal appln. rate.



**Table 1. Summary use information for clothianidin, including current uses (not shaded) and proposed uses (shaded gray and bolded) [from proposed labels for Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-1017 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152), Belay 16WSG (EPA Reg. No. 59639-153), Sepresto 75WS<sup>3</sup> (EPA Reg. No. 264-XXX) and PROCEED™ Optimum<sup>4</sup> (EPA Reg. No. 264-XXX)].**

PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A) <sup>12</sup>	SEASONAL APP. RATE (lb. a.i./A)	Comments
Arena 50WDG	Residential apple & pear trees	NA	NA	0.188	0.2	Apply by ground in 200 gal solution/ A
Arena 50WDG,+ V-10170 2.13SC	Non-bearing fruits & nut trees (in landscapes not for commercial prod.)	NA	NA	0.2	0.2	+Apply in 200 gal soln/ A
Arena 50WDG	Containerized Ornamental Plants in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	2 oz prod/100 gal water, drench application
Arena 50WDG	Ornamentals in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	1.26 oz prod/100 gal water, foliar application
V-10170 2.13SC	Ornamentals	NA	NA	NS	0.4	2.4 oz prod/100 gal water, foliar application
V-10170 2.13SC	Ornamentals grown in flat benches or beds	NA	NA	0.21	0.4	*2.4 oz product/7500 sq ft
Arena 50WDG	In-Ground Plants in Production Greenhouse and Field Nurseries	NA	NA	NS	0.4	Shrubs-2.4 g per ft of hght; Multi-Trunk Trees 4.8 g/cumulat. inch of trunk diameter at breast hght (soil drench or soil injection)
Arena 50WDG	Ornamentals in Commercial and Residential Outdoor Landscapes and Interior Plantscapes	NA	NA	NS	0.4	Foliar (1.26 oz prod/ 100 gal water)
						Soil drench or soil injection - Shrubs-2.4 g per ft of hght; Multi-Trunk Trees 4.8 g/cumulat. inch of trunk diameter at breast hght
				0.4	0.4	Soil applic. for plants grown in beds



**Table 1. Summary use information for clothianidin, including current uses (not shaded) and proposed uses (shaded gray and bolded) [from proposed labels for Arena 50WDG (EPA Reg. No. 59639-152), V-10170 2.13 SC (EPA Reg. No. 59639-150), V-1017 5FS (EPA Reg. No. 59639-151), CLUTCH 50 WDG (EPA Reg. No. 59369-152), Belay 16WSG (EPA Reg. No. 59639-153), Sepresto 75WS<sup>3</sup> (EPA Reg. No. 264-XXX) and PROCEED™ Optimum<sup>4</sup> (EPA Reg. No. 264-XXX)].**

PURPOSE/ SOURCE	USE	oz a.i./ 100 lb seed	oz a.i./ 1000 seed	MAX. IND. APP. RATE (lb. a.i./A) <sup>12</sup>	SEASONAL APP. RATE (lb. a.i./A)	Comments
CG = Crop Group; CSG = Crop Sub-Group; NA = Not Available; N/A = Not Applicable; NS = Not Specified; No aerial applications are allowed.						
1.	Seeding rate 131 lb seeds/A for wheat (representative crop); Source: <a href="http://www.uky.edu/Ag/Wheat/seedrate.html">http://www.uky.edu/Ag/Wheat/seedrate.html</a>					
2.	Seeding rate 1600-2200 lb seeds/A, source: <a href="http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/potato.html">http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/potato.html</a>					
3.	Sepresto 75WS is a combination product, containing clothianidin (56.25%) and imidacloprid (18.75%).					
4.	PROCEED™ OPTIMUM is a combination product, containing clothianidin (1.46% a.i.), and prothioconazole, tebuconazole and methalaxil.					
5.	Carrots, representative crop, source for approximate seeding rate: <a href="http://pmep.cce.cornell.edu/piap/carrot96/agpractices.html">http://pmep.cce.cornell.edu/piap/carrot96/agpractices.html</a> - and <a href="http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/carrot.html">http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/carrot.html</a> (23000 seeds/oz and 2-2.5 lb seeds/A => 920,000 seeds/A; app rate for carrots 0.0042 oz/1000 seeds => 0.24 lb a.i./A)					
6.	Onions, representative crop, source for approximate seeding rate: <a href="http://www.ag.ndsu.edu/pubs/alt-ag/onions.htm">http://www.ag.ndsu.edu/pubs/alt-ag/onions.htm</a> (8000 seeds/oz and 2-4 lb/A => 512000 seeds/A; app. rate for onions 0.006 oz a.i./1000 seeds, => 0.19 lb a.i./A)					
7.	Lettuce, representative crop, source of approximate seeding rate: <a href="http://www.ipmcenters.org/cropprofiles/CP_form.cfm">http://www.ipmcenters.org/cropprofiles/CP_form.cfm</a> (ultimately, 43000 plants/A => 0.075 lb a.i./A)					
8.	Same source as above (7). In CA about 44,000 plants cabbage /A => 0.11 lb a.i./A					
9.	Same source as above (7): In FL, maximum plant density of tomatoes is around 4,840/A; for tomatoes, the max. application rate is 0.00348 oz a.i./1000 seed => 0.001 lb a.i./A (note, transplants are not considered)					
10.	Same source as above (7), in FL, cucumbers maximum plant population is 21,780/A => 0.046 lb a.i./A					
11.	<a href="http://www.ces.purdue.edu/extmedia/AY/AY-217-W.pdf">http://www.ces.purdue.edu/extmedia/AY/AY-217-W.pdf</a> Max seeding rate 210,025 seeds/A; <a href="http://www.ipm.iastate.edu/ipm/icm/1998/10-12-1998/lowersoycost.html">http://www.ipm.iastate.edu/ipm/icm/1998/10-12-1998/lowersoycost.html</a> 2000-4000 seeds/lb					
12.	For seed treatment, the maximum individual application rate is the estimate of the equivalent application rate of the active ingredient in the field, assuming that the a.i. is uniformly distributed in the field.					
13.	Data obtained from previously issued assessments.					





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 04 2009

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

**MEMORANDUM**

**SUBJECT:** BEAD Review of the Benefits of Proposed Sepresto® Seed Treatment Product on Tomatoes, Peppers, Cucumbers, Squash and Melons (DP # 367429)

**FROM:** David W Brassard, Senior Entomologist *David W Brassard*  
Biological Analysis Branch  
Biological and Economic Analysis Division (7503C)

**THRU:** Arnet Jones, Branch Chief *Arnet Jones*  
Biological Analysis Branch  
Biological and Economic Analysis Division (7503C)

**TO:** Kable Davis, Reviewer  
Venus Eagle, Risk Manager  
Meredith Laws, Chief  
Insecticide Rodenticide Branch  
Registration Division (7505P)

Product Review Panel Date: September 30, 2009

**SUMMARY**

Bayer CropScience is requesting to register a new insecticide seed treatment product (Sepresto® 75 WS) containing a mixture of two neonicotinoids, imidacloprid and clothianidin, on 17 vegetable crops for control of a variety of early season insect pests. Because neonicotinoids are under Agency scrutiny due to pollinator concerns, BEAD was asked to conduct a benefits assessment for this product on tomatoes, peppers, cucumbers, squash and melons.

Sepresto® effectively controls early season infestations of aphids, thrips, leafminers, and other pests for 35 to 70 days after application. There are no seed treatment products currently registered for control of these early season pests on tomatoes, peppers, cucumbers, squash, and melons. Currently growers have to rely on at plant soil insecticides to control early season pests. At-plant soil insecticides are typically applied by specialized equipment at higher application rates which results in higher insecticide and application costs. Additionally, the availability of an



effective and convenient seed treatment product will likely result in a greater proportion of vegetables being treated for early season insect pests which could result in improved vegetable quality and yield for many growers. BEAD concludes that the availability of Sepresto® seed treatment will result in tangible benefits to growers.

BEAD's review also concludes that the inclusion of imidacloprid into the formulation contributes very little to the overall efficacy of the product.

## Background

Bayer CropScience is requesting to register a new insecticide seed treatment product (Sepresto® 75 WS) containing a mixture of two neonicotinoids, imidacloprid (18.75%) and clothianidin (56.25%). The proposed labeling lists 17 vegetable crops and claims control of aphids, whiteflies, thrips, leafminers, flea beetles, wireworms and a number of other insect pests. The registrant claims that the reason for combining the two active ingredients was because of increased efficacy. Because neonicotinoids are under Agency scrutiny due to pollinator concerns, BEAD was asked to conduct a benefits assessment for this product.

BEAD met with Meredith Laws of the Registration Division (RD) to discuss this request and BEAD agreed to look at the crops proposed on the label that would produce flowers during the growing season and thus attract pollinators under typical growing conditions. The agreed upon list included tomatoes, peppers, cucumbers, squash and melons. RD also had concerns about the utility of combining two neonicotinoids in a single product.

The proposed labeling for Sepresto® on tomatoes, peppers, cucumbers, squash and melons recommends application rates ranging from 0.05 to 1.32 grams active ingredient per 1000 seeds. These rates are equivalent to application rates ranging from 0.01 to 0.3 pounds active ingredient per acre (lbs ai/A). Refer to table 1 for more specific information.

**Table 1. Calculation of Application Rates for Sepresto® seed treatments on Cucumber, Melon, Squash, Pepper, and Tomato.**

Crop	# seeds/lb	lbs seed planted/A	# seed planted/A*	grams ai/1000 seed	lb ai/A
Cucumber	15,000-17,600	1-5	16,300-81,500	1.32	0.05-0.24
Melon	11,200-22,800	1-3	17,000-51,000	1.32	0.05-0.15
Squash, summer	3,200 - 6,320	3-6	14,280-28,560	1.32	0.04-0.08
Squash, winter	1,600 - 5,000	2-4	6,600-13,200	1.32	0.02-0.04
Pepper	64,000 - 75,760	0.5 - 3	39,940-209,640	0.66	0.05-0.3
Tomato	144,000 - 183,680	0.5-2	81,920-327,680	0.05-0.133	0.01-0.1

\* computed by multiplying the average number of seeds per pound by the range of the number of pounds of seed planted per acre

Source: OSU, 2009, Sepresto 75 WS proposed label, 2009; Tadayon and Dole, 2004



## Efficacy of Proposed Formulation

This product was submitted as a joint review with Health Canada's Pest Management Regulatory Agency (PMRA). As part of their review, PMRA reviewed efficacy data submitted by Bayer in support of Sepresto. PMRA's efficacy review concluded that Sepresto® seed treatments provided good to excellent control on some pests (e.g. aphids and thrips), poor control of others (e.g. leafminers and cucumber beetles), and that some pest claims not supported by data (e.g. flea beetles, beet armyworm, seedcorn maggot, or whiteflies). See Table 1 and the following paragraph for a summary of their review.

On tomato, the PMRA concluded that Sepresto® provides good control of thrips but performed poorly against leafminers. The registrant did not submit any data for flea beetles, beet armyworm, or whiteflies. On peppers, the PMRA concluded that Sepresto® provides good control of aphids and leafminers. The registrant did not submit any data for thrips, flea beetles, beet armyworm, or whiteflies. On summer squash and cucumber, the PMRA concluded that Sepresto® provides good to excellent control of aphids, good control of thrips, and poor control of cucumber beetles. The registrant did not submit any data for seedcorn maggot control on these crops.

**Table 2. Summary of PMRA's efficacy review of Sepresto® Seed Treatments**

Crop	Efficacy Summary	Pests not supported by efficacy data
Tomato	Aphids: 87-89% control for 17-35 days Thrips: 80% control for 70 days Leafminers: 37.5% control	flea beetles, beet armyworm, or whiteflies
Pepper	Aphids: 82-89% control for 52 days. Leafminers: 83% control for 49 days	thrips, flea beetles, beet armyworm, or whiteflies
Cucumber	Aphids 88-100% control for 54-61 days cucumber beetle: 42-57% for 16-21 days	seedcorn maggot, thrips
Summer squash	Aphids: 82-100% control of aphids for 35-47 days Thrips: 77-87% of for 39 days.	cucumber beetle, seedcorn maggot
Winter squash	No data	Aphids, cucumber beetle, seedcorn maggot, thrips
Melon	No data	

In regard to the lack of efficacy data for flea beetles and seedcorn maggot, BEAD's review of efficacy data for clothianidin seed treatment products on canola and corn suggest that Sepresto® will also be effective against these pests (Brassard 2002; Brassard and Alsadek, 1999). BEAD has not seen any data on the efficacy of Sepresto® against beet armyworm or whiteflies.

## Benefits Associated with the Availability of a Sepresto® Seed Treatment Product

There are no seed treatment products currently registered for control of these pests on tomatoes, peppers, cucumbers, squash, and melons. Currently growers have to rely on at plant soil insecticides such as bifenthrin, diazinon, dinotefuran, imidacloprid, or thiamethoxam to control these pests (OSU, 2009). These at-plant insecticide applications are typically applied by specialized equipment at higher application rates than Sepresto® and thus are likely to result in higher insecticide and application costs. For example, imidacloprid at-plant soil treatments to summer and winter squash are made at the application rate of 0.25 to 0.375 pounds active



ingredient per acre (lbs ai/A). In comparison, Sepresto® is applied to these crops at the rate of 0.02 to 0.08 lbs ai/A. In addition to reducing application costs, the convenience of applying treated seed (as opposed to making at-plant insecticide applications with specialized equipment) will likely result in a greater proportion of vegetables being treated for early season insect pests which could result in improved vegetable quality and yield for many growers. BEAD concludes that the availability of Sepresto® seed treatment will result in tangible economic benefits to growers.

#### **Rationale for Combining Two Neonicotinoids in a Single Product.**

Bayer's explanation for including two active ingredients with the same mode of action is that, although both clothianidin and imidacloprid have a broad spectrum of activity, some species are more or less tolerant to clothianidin and imidacloprid can improve the spectrum of insect control provided by clothianidin alone.

BEAD's review concludes that imidacloprid contributes very little to the overall efficacy of the product. Imidacloprid constitutes only about one-fourth of the total active ingredient (ai) contained in the product. Additionally, based on seed treatment rates for single active ingredient products containing clothianidin or imidacloprid on canola, imidacloprid is applied at rates ranging 2.5 to 2.67 times higher than clothianidin seed treatment products (Poncho 600 label, 2009; Gaucho 480 label, 2007). BEAD's previous review of canola flea beetle efficacy data concluded that thiamethoxam was more effective than imidacloprid, even at the lower application rates (Brassard and Alsadek, 1999). Also, the registrant provided no supporting evidence that imidacloprid has a broader spectrum of insect control than clothianidin. Based on the percentage of imidacloprid in the product and application rates on canola, BEAD estimates that imidacloprid's contribution only amounts to 10% of the overall efficacy of the Sepresto® product.

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WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

PC Code: 129099  
DP Barcode: D357013 and D357014  
Date: July 22, 2009

**MEMORANDUM**

**SUBJECT:** Imidacloprid Registration of New Products Sepresto 75WS and New Use for GAUCHO 550SC

**FROM:** José L. Meléndez, Chemist  
N.E. Federoff, Wildlife Biologist  
Environmental Risk Branch V  
Environmental Fate and Effects Division (7507P)

**THROUGH:** Mah T. Shamim, Branch Chief  
Environmental Risk Branch V  
Environmental Fate and Effects Division (7507P)

**TO:** Kable Davis, Risk Manager Reviewer  
Venus Eagle, Risk Manager  
Meredith Laws, Branch Chief  
Insecticide-Rodenticide Branch  
Registration Division (7505P)

EFED has conducted a revision of the proposed new uses for imidacloprid. At this time, a new ecological risk assessment is not required because the previously issued assessments cover the new uses. The risks found in previous assessments should be similar for the new uses. The previous assessments are the following: D334030, D311925 and D313218.

***Background:***

The registrant of imidacloprid, Bayer CropScience, is applying for registration of a new multi-active ingredient product for seed treatment and for one new use of the chemical. This review covers only the active ingredient imidacloprid.

The new multi-active ingredient product for seed treatment is Sepresto 75WS (EPA Reg.



No. 264-XXX), containing clothianidin (56.25%) and imidacloprid (18.75%). This product is for the treatment of seeds of root vegetables (CG 1), bulb vegetables (CG 3), leafy green vegetables (CSG 4A), brassica (cole) vegetables (CG 5), fruiting vegetables (CG 8), cucurbit vegetables (CG 9), cereal grains (except rice) (CG 15) and potato seed pieces. In addition, the registrant applied for a new use for GAUCHO 550SC (EPA Reg. No. 264-827) on bulb vegetables (CG 3-07).

#### ***Previous Assessments Cover Current Uses***

EFED has previously conducted various assessments of uses of imidacloprid. An assessment of the uses of the chemical for seed treatment was conducted for peanuts, kava, millet, oat and artichoke and issued on 3/7/06 (D334030). The same assessment covered uses of the chemical on caneberries (CSG 13A) and raspberries (maximum rate of 0.5 lb a.i./A). Also an assessment for soybean seed treatment was issued on 6/9/05 (D313218). In another review, aerial & ground applications on cotton, potato, tobacco, head and stem brassica vegetables, root tuberous and corm vegetables, strawberry, bushberry, citrus, grape, hop, pecan, pome fruit, stone fruit, pear, tropical fruits, poplar and cottonwood tree were assessed (review dated 4/12/06, D311925). In the assessment, various crops were assessed, with seasonal application rates of up to 0.5 lb a.i./A. These included tree nuts, berries and coffee.

In the current petition, a maximum seasonal application rate of 0.5 lb a.i./A is proposed for crops like root and tuberous vegetables, leafy green vegetable, brassica (cole) vegetables, fruiting vegetables, cucurbit vegetables and bulb vegetables. The aquatic exposure related to the new crops should be similar to that of previous crops with similar application rates and the risks should be similar. For spray applications, the terrestrial exposure should also be similar to the previous reviews, with similar risk concerns.

Also, the exposure to terrestrial organisms related to the new uses should be similar to the ones for previously assessed uses, such as berries, tree nuts, and coffee (maximum application rate 0.5 lb a.i./A), and the risk concerns should also be similar.

The new product, Sepresto 75WS is for seed treatment only. Under previous assessments, it was suggested that imidacloprid has the potential to cause acute risk to small seed-eating endangered avian species as well as to endangered and non-endangered small mammals. There seems to be evidence of avian repellency to imidacloprid treated seed which may mitigate some risk to seed-eating avian species. However, to what extent risk would be mitigated is still an uncertainty. A listing of endangered species was not attached due to the volume of such a listing because of the multitude of crop uses.

Acute toxicity studies with honeybees show that imidacloprid is very highly toxic to nontarget insects ( $LD_{50} = 0.0039 - 0.078 \mu\text{g}/\text{bee}$ ). This is a concern for pollinators because imidacloprid is a systemic pesticide which has been shown to translocate into the nectar and pollen of crop plants grown from treated seed. Studies with ornamental plants have shown that imidacloprid may also translocate into plant parts when the chemical is applied to the soil around the base of the plants. In these studies with ornamentals, detectable residues were found in flowers and leaves as long as 540 days after application to the soil.



## Appendix A. Summary of Use Information for Imidacloprid

**Table 1. Summary use information for imidacloprid, including proposed (shaded yellow) and current (not shaded) uses [labels for GAUCHO® 550SC (EPA Reg. No. 264-827) and Sepresto 75WS (EPA Reg. No. 264-XXX, Proposed)].**

PURPOSE/ SOURCE	USE	a.i. oz/ 1000 seed	APP. RATE max. lb a.i./ A/applic.	APP. RATE lb. a.i./ A/season	LABELED METHODS OF APPLICATION <sup>4</sup>	COMMENTS
Sepresto 75WS	Root & Tuber veg. (CG 1)	0.00525	0.30 <sup>5</sup>	0.5	Seed treatment	
GAUCHO 550SC	Root veg. (CSG 1B except sugarbeet + kava)	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Tuberous & Corm veg. (CSG 1C)	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Sugarbeet (CA only)	N/A	0.18	0.18	Seed treatment, soil	
Sepresto 75WS	Potato Seed pieces	N/A	0.09 <sup>2</sup>	0.09 <sup>2</sup>	Seed treatment	0.35 oz prod/100 lb seed; 7.7 oz prod/A <sup>2</sup>
GAUCHO 550SC	Potato & Potato Seed Piece Treatment	NA	0.31	0.31	Seed treatment, soil, foliar	
Sepresto 75WS	Leafy Greens veg. (CSG 4A)	0.0094	0.025 <sup>6</sup>	0.5	Seed treatment	
GAUCHO 550SC	Leafy veg. (CSG 4A plus watercress)	N/A	0.38	0.38	Seed treatment, soil, foliar	
Sepresto 75WS	Brassica (Cole) Leafy veg (CG 5)	0.01387	0.038 <sup>7</sup>	0.5	Seed treatment	
GAUCHO 550SC	Brassica (Cole) Leafy veg (CG 5)	N/A	0.38	0.38	Seed treatment, soil, foliar	
Sepresto 75WS	Fruiting veg. (CG 8)	0.00581	0.00035 <sup>8</sup>	0.5	Seed treatment	
GAUCHO 550SC	Fruiting veg. (CG 8) (except pepper & okra)	N/A	0.38	0.38	Seed treatment, soil, foliar	Additional use for planthouses
	Pepper & Okra	N/A	0.5	0.5		
Sepresto 75WS	Cucurbit veg. (CG 9)	0.011	0.045 <sup>9</sup>	0.5	Seed treatment	



**Table 1. Summary use information for imidacloprid, including proposed (shaded yellow) and current (not shaded) uses [labels for GAUCHO® 550SC (EPA Reg. No. 264-827) and Sepresto 75WS (EPA Reg. No. 264-XXX, Proposed)].**

PURPOSE/ SOURCE	USE	a.i. oz/ 1000 seed	APP. RATE max. lb a.i./ A/applic.	APP. RATE lb. a.i./ A/season	LABELED METHODS OF APPLICATION <sup>4</sup>	COMMENTS
GAUCHO 550SC	Cucurbit veg. (CG 9)	N/A	0.38	0.38	Seed treatment, soil, foliar	Addl use for planthouses
Sepresto 75WS	Bulb veg. (CG 3)	0.0024	0.064 <sup>10</sup>	0.5	Seed treatment	
GAUCHO 550SC	Bulb veg. (CG 3-07)	N/A	0.5	0.5	Seed treatment, soil, foliar	
Sepresto 75WS	Cereal Grain (CG 15 w/o rice)	N/A	0.03 <sup>1</sup>	0.03 <sup>1</sup>	Seed treatment	2.0 oz/100 lb seed; 2.6 oz/A <sup>1</sup>
GAUCHO 550SC	Cotton	N/A	0.33	0.5	Seed treatment, soil, foliar	Max. 6 applics. a.i./ season
GAUCHO 550SC	Peanut	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Tobacco	N/A	NS	0.5	Soil, foliar	Max. 1.2 oz prod/ 1000 plants
GAUCHO 550SC	Greenhouse veg. (cucumber & tomato)	N/A	NA	NA <sup>3</sup>	Foliar	0.6 oz product/ 1000 plants
GAUCHO 550SC	Globe Artichoke	N/A	0.5	0.5	Seed treatment, soil, foliar	
GAUCHO 550SC	Herbs (CS 19A)	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Leafy Petiole veg. (CSG 4B)	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Legume veg. (CG 6 except dry soybean)	N/A	0.38	0.38	Seed treatment, soil, foliar	
GAUCHO 550SC	Strawberry	N/A	0.5	0.5	Soil, foliar	Do not use both app. methods in the same season.
	Use Post-Harvest	N/A	0.38	0.38	Soil, foliar	



**Table 1. Summary use information for imidacloprid, including proposed (shaded yellow) and current (not shaded) uses [labels for GAUCHO® 550SC (EPA Reg. No. 264-827) and Sepresto 75WS (EPA Reg. No. 264-XXX, Proposed)].**

PURPOSE/ SOURCE	USE	a.i. oz/ 1000 seed	APP. RATE max. lb a.i./ A/applic.	APP. RATE lb. a.i./ A/season	LABELED METHODS OF APPLICATION <sup>4</sup>	COMMENTS
<p>NA = Not Available; N/A = Not Applicable; NS = Not Specified; For GAUCHO 550SC, seed treatment is in the field at planting or shortly thereafter.</p> <p>1. Seeding rate 131 lb seeds/A for wheat (representative crop); Source: <a href="http://www.uky.edu/Ag/Wheat/seedrate.html">http://www.uky.edu/Ag/Wheat/seedrate.html</a></p> <p>2. Seeding rate 1600-2200 lb seeds/A Source: <a href="http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/potato.html">http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/potato.html</a></p> <p>3. Greenhouse uses are not assessed by EFED.</p> <p>4. General instructions for GAUCHO 550SC: Aerial applications of GAUCHO 550SC are not allowed. The product may be applied with ground equipment or via chemigation. Applications of GAUCHO 550SC should direct product into the seed or root zone of crop. Broadcast foliar applications are only recommended to seedling flats or trays, or where product is intended to be washed from foliage to soil prior to drying on foliage.</p> <p>5. Carrots, representative crop, source for approximate seeding rate: <a href="http://pmep.cce.cornell.edu/piap/carrot96/agpractices.html">http://pmep.cce.cornell.edu/piap/carrot96/agpractices.html</a> - and <a href="http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/carrot.html">http://aggie-horticulture.tamu.edu/extension/vegetable/cropguides/carrot.html</a> (23000 seeds/oz and 2-2.5 lb seeds/A =&gt; 920,000 seeds/A; app rate for carrots 0.00525 oz/1000 seeds =&gt; 0.30 lb a.i./A)</p> <p>6. Lettuce, representative crop, source of approximate seeding rate: <a href="http://www.ipmcenters.org/cropprofiles/CP_form.cfm">http://www.ipmcenters.org/cropprofiles/CP_form.cfm</a> (ultimately, 43000 plants/A =&gt; 0.025 lb a.i./A)</p> <p>7. Same source as above (6). In CA about 44,000 plants cabbage /A =&gt; 0.0038 lb a.i./A</p> <p>8. Same source as above (6): In FL, maximum plant density of tomatoes is around 4,840/A; for tomatoes, the max. application rate is 0.00116 oz a.i./1000 seed =&gt; 0.00035 lb a.i./A (note, transplants are not considered)</p> <p>9. Same source as above (6), in FL, cucumbers maximum plant population is 21,780/A =&gt; 0.015 lb a.i./A</p> <p>10. Onions, representative crop, source for approximate seeding rate: <a href="http://www.ag.ndsu.edu/pubs/alt-ag/onions.htm">http://www.ag.ndsu.edu/pubs/alt-ag/onions.htm</a> (8000 seeds/oz and 2-4 lb/A =&gt; 512000 seeds/A; app. rate for onions 0.0020 oz a.i./1000 seeds. =&gt; 0.064 lb a.i./A)</p>						



# Bayer CropScience



September 16, 2008 (via e-mail)

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD), Ms. Linda Arrington (Team Leader, N&MF), Ms. Mary Waller (PM 21, RD)

**Re: Response to 21 Day Content Screen Review Worksheet**

**Sepestro 75 WS (EPA File Symbol: 264-RNIR)**

Dear Ms. Waller,

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Bayer CropScience is herein submitting the following requested documents as listed in the PRIA 2 – 21 Day Content Screen Review Worksheet (attached)

- (1) Revised Form 8570-1 to include packaging and container information in Section III
- (2) Revised data matrix for both Agency and Public Use copies to include the reports for imidacloprid
- (3) Revised Form 8570-27

Please contact me at 919-549-2634 or at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) if you have any questions regarding this submission.

Sincerely,

Jamin Huang  
Product Registration Manager

Attachments





United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 264-XXXX	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sepresto 75 WS	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer Cropscience 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

REGFEE: PRIA II R310 (to register a new end-use product, Sepresto 75 WS, \$ 4,360. Request for a 15 month (instead of 6 month) review to be in sync with other PRIA actions for Sepresto 75 WS  
JUSTIFICATIONS: As one of the 6 PRIA II actions to register a new product, Sepresto 75 WS, for seed treatment uses on a number of new crops. Please see the enclosed cover letter for details.  
CONTACT: Jamin Huang e-mail address: jamin.huang@bayercropscience.com

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container <i>revised 9/15/08 JH</i>	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
				<input type="checkbox"/> Paper	
				<input checked="" type="checkbox"/> Other (Specify) <i>fiber</i>	
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container <i>5 lb and 25 lb</i>		5. Location of Label Directions <input checked="" type="checkbox"/> ON CONTAINER <i>inside</i>	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jamin Huang, Ph.D.		Title Registration Product Manager		Telephone No. (Include Area Code) 919-549-2634	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					6. Date Application Received (Stamped)
2. Signature <i>Jamin Huang</i>		3. Title Registration Product Manager			
4. Typed Name Jamin Huang, Ph.D.		5. Date August 1, 2008			





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

Jamin Huang, Ph.D

Date: 9/11/2008

Bayer Crop Science

2 T.W. Alexander Drive

P.O. Box 12014

Research Triangle Park, NC 27709

Your email: jamin.huang@bayercropscience.com

Subject: File Symbol/Registration No.

264-RNIR (Dec # 399489)  
264-RNIE (Dec # 399587)

Dear Mr./Ms. Dr. Huang

The above referenced PRIA application was screened by the Registration Division's Completeness Check Team and determined to be deficient. Please see the enclosed copy of our screening checklist for the specific deficiency.

You must submit corrections within 7 days of the date of this notice, to the Completeness Check Team. Include the following Decision Number on your cover letter with the words "Resubmission - For RD's Completeness Check Team" to identify your package.

Decision #D 399489 & 399587

RESUBMISSION - For RD's Completeness Check Team

→ You may send in corrections via fax or e-mail, provided that the material is not Confidential Business Information. Our fax number is (703) 347-8932. Our e-mail address is: OPP\_RD\_Completeness\_Screening@epa.gov.

If you cannot meet this time frame, please contact us for further discussions on this matter. My telephone number is (703) 308 - 9354.

Sincerely,

*Mary J. Waller*

Completeness Check Team  
Registration Division (7505P)  
U.S. EPA, One Potomac Yard  
2777 S. Crystal Drive  
Arlington, VA 22202

Attachment



Food use

## PRIA 2 - 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date:

4/9/08  
8/20/08

Experts In-Processing Signature:

C. [Signature]

Date 9/5/09

Fee Paid: Yes

✓

Division management contacted on issues No

Yes

Date

EPA Reg. Number: 264-KNIR		EPA Receipt Date: 8/20/08				
Items for Review			Yes	No	N/A*	
1	Application Form (EPA Form 8570-1) signed & complete including package type <i>missing Section III information. Registrant says they have determined the packaging and container information yet.</i>			✓	✓	
2	Confidential Statement of Formula all boxes completed, form signed, and dated (EPA Form 8570-4)			✓		
	a) All inerts, except fragrances, approved for food and non food proposed uses (see Footnote A)	yes	no			
3	Certification with Respect to Citation of Data (EPA Form 8570-34) completed and signed (N/A if 100% repack)			✓		
	Certificate and data matrix consistent <i>data matrix needs correction</i>				✓	
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
	If applicable, is there a letter of Authorization for exclusive use only.					✓
4	Formulator's Exemption Statement (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)				✓	
	Data Matrix (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack) *			✓		
5	a) Selective Method (Fee category experts use)	yes	no			
	b) Cite-All (Fee category experts use)					
	c) Applicant owns all data (Fee category experts use)					
6	5 Copies of Label (Electronic labels on CD are encouraged) <i>e-submission</i>					
7	Is the data package consistent with PR Notice 86-5 <i>Failed first time Second time - OK</i>			✓		
8	Notice of Filing (link to included with petitions)			✓		

\* Note: Dr. Huang said he submitted Agency Internal Copy to submit. PM team will need to get public file copy out of Documentum.



9	If applicable for conventional applications, reduced risk rationale			✓
10	Required Data and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

(FES)  
Formulators Exemption Statement: You cannot claim a formulator's exemption for your own product (264-755). Submit new FES for [REDACTED] only.

Data matrix: Revise data matrix to list all <sup>imidacloprid</sup> data necessary to support registration of 264-RNIR and list all ~~new~~ new use data for clothianidin. Since you are purchasing a registered [REDACTED] from another source, you do not need to list that data.

Application Form: I have discussed this item with other screeners and we agree that you must submit a complete application Form, Section III. It is unacceptable to submit an application without this information.

\*Product ingredient source information may be entitled to confidential treatment\*

\* N/A - Not Applicable



#### Footnotes

A. This consideration does not apply to PRIA applications that include a request to approve an inert in the fee category. For these PRIA actions, information needs to be submitted to enable the Agency to review the inert approval request and will be a subject of the 21 day content screen. For other types of actions and for fragrances, the answer is only for the Agency's information and current policies, processes, and procedures should be consulted. This worksheet will be updated in the future to be consistent with current policies.

If brand, trade, or proprietary names are being used for some inert ingredients listed on the CSF, alternate names or additional information on the nature of the ingredient(s) should be provided to allow the Agency to determine whether the inert has been approved.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Refer to the list of data requirements. Biopesticide applicants were advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	EPA File Symbol/Registration Number 264-RNIR
	Product Name Sepresto 75 WS
	Date of Confidential Statement of Formula (EPA Form 8570-4) 08/01/2008

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

clothianidin and imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Clothianidin		
*Product ingredient source information may be entitled to confidential treatment*		
Signature 	Name and Title Jamin Huang, Registration Manager	Date 09/11/2008

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for Reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 1 of 1

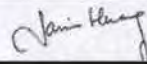
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Sepresto 75 WS</b>					
830.1550	Product Identity and Composition	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1600	Description of Material Used to Produce the Product	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1620	Decription of Product Process	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1650	Decription of Formulation Process	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1670	Discussion of Formation of Impurities	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1700	Preliminary Analysis	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1750	Certified Limits	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1800	Enforcement Analytical Method	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6302	Color	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6303	Physical State	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6304	Odor	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6317	Storage Stability	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6320	Corrosion Characteristics	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

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**DATA MATRIX**

Date: September 15, 2008

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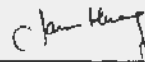
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.7000	pH of Water Solutions or Suspensions	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.7300	Density/Relative Density/Bulk Density	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
835.1240	Soil Column Leaching	47483002	Bayer Cropscience	OWN	M-270224-02-1 (METIX050-1)
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25 C	47483003	Bayer Cropscience	OWN	M-267329-02-1 (METIX051-1)
850.1735	Whole Sediment: Acute Freshwater Invertebrates	46826902	Bayer Cropscience	OWN	M-271041-01-1 (EBTIX063)
850.1950	Field Testing for Aquatic Organisms	47483004	Bayer Cropscience	OWN	M-044250-01-2 (DECO 082)
860.1300	Analytical Method	47483005	Bayer Cropscience	OWN	M-278059-01-1 (NT-001-P04-01)
830.1300	Validation report	47483006	Bayer Cropscience	OWN	M-289314-01-1 (RATY008) Lynx Number: RATY008
860.1300	Independent Laboratory Validation	47483007	Bayer Cropscience	OWN	M-283049-01-1 (RATY018)
860.1300	Outside Laboratory Validation	42556124	Bayer Cropscience	OWN	M-003302-01-1 (103214)
860.1300	Clothiadin Multiresidue Method	47483008	Bayer Cropscience	OWN	M-272961-01-1 (RATY016)
860.1300	Imidacloprid Multiresidue Method	42556122	Bayer Cropscience	OWN	M-020722-01-2 (103840)
860.1380	Storage Stability Data	47483009	Bayer Cropscience	OWN	M-303705-01-1 (RATY015) Lynx Number: RATY015

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
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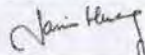
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1380	Storage Stability Data	43487301~~	Bayer Cropscience	OWN	M-090224-01-2 (103949-3)
860.1380	Storage Stability Data	47483010	Bayer Cropscience	OWN	M-090199-01-2 (103949-4)
860.1380	Storage Stability Data	43197203~~ 47483011	Bayer Cropscience	OWN	M-090164-01-1 (103237-2)
860.1500	Potatoes	47483012	Bayer Cropscience	OWN	M-282086-01-1 (RATIIY004)
860.1500	Potatoes	47483013	Bayer Cropscience	OWN	M-304969-01-1 (AAFC04-001 R)
860.1500	Root Vegetables	47483014	Bayer Cropscience	OWN	M-304701-01-1 (RATIP043) Lynx Number: RATIP043
860.1500	Bulb Vegetables	47483015	Bayer Cropscience	OWN	M-304371-01-1 (RATIP044) Lynx Number: RATIP044
860.1500	Bulb Vegetables	47483016	Bayer Cropscience	OWN	M-304592-01-1 (RATIIY020) Lynx Number: RATIIY020
860.1500	Leafy Greens	47483017	Bayer Cropscience	OWN	M-304730-01-1 (RATIL001) Lynx Number: RATIL001
860.1500	Brassica Leafy Vegetables	47483018	Bayer Cropscience	OWN	M-304704-01-1 (RATIL002) Lynx Number: RATIL002
860.1500	Fruiting Vegetables	47483019	Bayer Cropscience	OWN	M-304551-01-1 (RATIP046) Lynx Number: RATIP046
860.1500	Cucurbit Vegetables	47483020	Bayer Cropscience	OWN	M-300700-01-1 (RATIP045)

Signature



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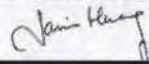
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

					Lynx Number: RATIP045
860.1500	Wheat	47483021	Bayer Cropscience	OWN	M-303764-01-1 (RATIIY013) Lynx Number: RATIIY013
860.1520	Potato Processed Commodities	47483022	Bayer Cropscience	OWN	M-282378-01-1 (RATIIY005)
860.1520	Tomato Processed Commodities	47483023	Bayer Cropscience	OWN	M-304478-01-1 (RATIP041) Lynx Number: RATIP041
860.1520	Wheat Processed Commodities	47483024	Bayer Cropscience	OWN	M-304174-01-1 (RATIP037) Lynx Number: RATIP037
860.1900	Soybeans (Rotational Crop)	47496202	Bayer Cropscience	OWN	M-304695-01-1 (RATIIY011) Lynx Number: RATFP001
870.1100	Acute Oral Toxicity	47483025	Bayer Cropscience	OWN	M-301714-01-1 (24696) Lynx Number: TXTIP001
870.1200	Acute Dermal Toxicity	47483026	Bayer Cropscience	OWN	M-292803-01-2 (AT04102) Lynx Number: TXTIX111
870.1300	Acute Inhalation Toxicity	47483027	Bayer Cropscience	OWN	M-294053-01-2 (AT04206) Lynx Number: TXTIX122
870.2400	Acute Eye Irritation	47483028	Bayer Cropscience	OWN	M-292824-01-2 (AT04106) Lynx Number: TXTIX112
870.2500	Acute Dermal Irritation	47483029	Bayer Cropscience	OWN	M-292823-01-2 (AT04107) Lynx Number: TXTIX113

Signature



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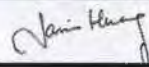
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.2600	Skin Sensitization	47483030	Bayer Cropscience	OWN	M-293656-01-2 (AT04180) Lynx Number: TXTIX114
875.1100	Dermal Exposure--Outdoor	47483031	Bayer Cropscience	OWN	M-043846-01-2 (MR-565/01)
875.1100	Dermal Exposure--Outdoor	47483032	Bayer Cropscience	OWN	M-305114-01-1 (G201919)
875.1300	Inhalation Exposure--Outdoor	47483031	Bayer Cropscience	OWN	M-043846-01-2 (MR-565/01)
875.1300	Inhalation Exposure--Outdoor	47483032	Bayer Cropscience	OWN	M-305114-01-1 (G201919)
SUPP	Groundwater Exposure Assessment	47483033	Bayer Cropscience	OWN	M-304828-01-1 (RATY024) Lynx Number: RATY024
SUPP	Acute and Chronic Dietary Exposure Assessment	47483034	Bayer Cropscience	OWN	M-305112-01-1 (G201914)
SUPP	Assessment of worker exposure (Canada)	47483035	Bayer Cropscience	OWN	M-305586-01-1 (G201925)
<b>Imidacloprid</b>					
830.1550	Chemical identity	42055302	264	OWN	BR 1759 (TGAI)
830.1550	Chemical identity	43306001	264	OWN	BR 1879 (TGAI)
830.1550	Chemical identity	42256302	264	OWN	BR 1766 (Formulation)
830.1600	Statement of Composition	42055302	264	OWN	BR 1759 (TGAI)

Signature



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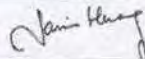
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.1600	Statement of Composition	42270801	264	OWN	BR 1785 (TGAI)
830.1600	Statement of Composition	43306001	264	OWN	BR 1879 (TGAI)
830.1600	Statement of Composition	42256302	264	OWN	BR 1766 (Formulation)
830.1670	Formation of impurities	42055302	264	OWN	BR 1759 (TGAI)
830.1670	Formation of impurities	42256302	264	OWN	BR 1766 (Formulation)
830.1700	Preliminary analysis	42055303	264	OWN	BR 1760 (TGAI)
830.1700	Preliminary analysis	42270802	264	OWN	BR 1786 (TGAI)
830.1700	Preliminary analysis	43306002	264	OWN	BR 1880 (TGAI)
830.1700	Preliminary analysis	42256302	264	OWN	BR 1766 (Formulation)
830.1750	Certification of limits	42055303	264	OWN	BR 1760 (TGAI)
830.1750	Certification of limits	43306002	264	OWN	BR 1880 (TGAI)
830.1750	Certification of limits	42256302	264	OWN	BR 1766 (Formulation)
830.1800	Analytical method	42055303	264	OWN	BR 1760 (TGAI)
830.1800	Analytical method	43213001	264	OWN	BR 1874 (TGAI)
830.1800	Analytical method	43306002	264	OWN	BR 1880 (TGAI)

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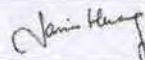
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.1800	Analytical method	42256302	264	OWN	BR 1766 (Formulation)
830.6301	Chemical and Physical Properties	42055304	264	OWN	BR 1761 (TGAI)
830.6301	Chemical and Physical Properties	42256302	264	OWN	BR 1766 (Formulation)
830.6302	Appearance	42055304	264	OWN	BR 1761 (TGAI)
830.6302	Appearance	42256302	264	OWN	BR 1766 (Formulation)
830.6303	Physical state	42055304	264	OWN	BR 1761 (TGAI)
830.6303	Physical state	42256302	264	OWN	BR 1766 (Formulation)
830.6304	Odor	42055304	264	OWN	BR 1761 (TGAI)
830.6304	Odor	42256302	264	OWN	BR 1766 (Formulation)
830.6313	Stability	42055304	264	OWN	BR 1761 (TGAI)
830.6315	Flammability	42055304	264	OWN	BR 1761 (TGAI)
830.6316	Explodability	42055304	264	OWN	BR 1761 (TGAI)
830.6317	Storage stability	42055304	264	OWN	BR 1761 (TGAI)
830.6317	Storage stability	42256302	264	OWN	BR 1766 (Formulation)
830.6320	Corrosion characteristics	42055304	264	OWN	BR 1761 (TGAI)

Signature



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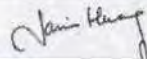
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.6320	Corrosion characteristics	42256302	264	OWN	BR 1766 (Formulation)
830.7000	pH	42055304	264	OWN	BR 1761 (TGAI)
830.7000	pH	42256302	264	OWN	BR 1766 (Formulation)
830.7200	Melting point	42055304	264	OWN	BR 1761 (TGAI)
830.7220	Boiling point	42055304	264	OWN	BR 1761(TGAI)
830.7300	Density	42055304	264	OWN	BR 1761 (TGAI)
830.7300	Density	43356302	264	OWN	BR 1761 (Formulation)
830.7560	Octanol / water partition	42055304	264	OWN	BR 1761 (TGAI)
830.7840	Solubility	42055304	264	OWN	BR 1761 (TGAI)
830.7950	Vapor pressure	42055304	264	OWN	BR 1761 (TGAI)
<b>Environmental Fate, Section 158.290</b>					
835.1230	Leaching / adsorption/desorption	42055338	264	OWN	Report No. 99199
835.1230	Leaching / adsorption/desorption	42055339	264	OWN	Report No. 99635
835.1230	Leaching / adsorption/desorption	42520801	264	OWN	Report No. 103816
835.1230	Leaching / adsorption/desorption	42520802	264	OWN	Report No. 103817

Signature



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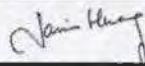
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

835.2120	Hydrolysis	42055337	264	OWN	Report No. 99708
835.2240	Photodegradation - water	42256376	264	OWN	Report No. 101956
835.2410	Photodegradation - soil	42256377	264	OWN	Report No. 100249
835.4100	Aerobic soil metabolism	42539201	264	OWN	Report No. 100140
835.4100	Aerobic soil metabolism	42539202	264	OWN	Report No. 100141
835.4100	Aerobic soil metabolism	42539203	264	OWN	Report No. 101955
835.4100	Aerobic soil metabolism	42539204	264	OWN	Report No. 103202
835.4100	Aerobic soil metabolism	45239301	264	OWN	Report No. PF 3321
835.4100	Aerobic soil metabolism	45239302	264	OWN	Report No. PF 3322
835.4200	Anerobic soil metabolism	42073501	264	OWN	Report No. 101241
835.4400	Anaerobic aquatic metabolism	42256378	264	OWN	Report No. 101346
835.6100	Terrestrial field dissipation	42256379	264	OWN	Report No. 101987
835.6100	Terrestrial field dissipation	42256380	264	OWN	Report No. 101988
835.6100	Terrestrial field dissipation	42256381	264	OWN	Report No. 101989
835.6100	Terrestrial field dissipation	42256382	264	OWN	Report No. 102603

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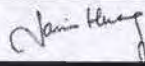
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

835.6100	Terrestrial field dissipation	42256383	264	OWN	Report No. 102604
835.6100	Terrestrial field dissipation	42256384	264	OWN	Report No. 101984
835.6100	Terrestrial field dissipation	42256385	264	OWN	Report No. 101981
835.6100	Terrestrial field dissipation	42734101	264	OWN	Report No. 103948
835.7100	Ground water - small prospective	43142501	264	OWN	Report No. 106426
835.7100	Ground water - small prospective	43315201	264	OWN	Report No.106426-1
835.7100	Ground water - small prospective	43449501	264	OWN	Report No. 106637
835.7100	Ground water - small prospective	44790102	264	OWN	Report No. 108791
835.7100	Ground water - small prospective	44790103	264	OWN	Report No. 108792
835.7100	Ground water - small prospective	45094701	264	OWN	Report No. 109383
835.7100	Ground water - small prospective	45094702	264	OWN	Report No. 109596
835.7100	Ground water - small prospective	45094703	264	OWN	Report No. 108939
835.7100	Ground water - small prospective	45858201	264	OWN	Report No. 110773
835.7100	Ground water - small prospective	45878701	264	OWN	Report No. 110889
835 None	Environmental fate summary	42734103	264	OWN	Report No. 105010

Signature



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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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USA

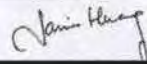
Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

**Wildlife and Aquatic Organisms,  
Section 158.490**

850.1010	Invertebrate toxicity - Daphnia	42055317	264	OWN	Report No. 100245
850.1010	Invertebrate toxicity - Amphipods	42256303	264	OWN	Report No. 101960
850.1010	Acute aquatic invertebrate toxicity - Chironomids	42256304	264	OWN	Report No. 101985
850.1025	Estuarine / marine toxicity - fish	42055318	264	OWN	Report No. 100354
850.1025	Estuarine / marine toxicity - mollusk	42256305	264	OWN	Report No. 101978
850.1025	Estuarine/marine toxicity - shrimp	42055319	264	OWN	Report No. 100355
850.1025	Estuarine/marine toxicity - shrimp	42528301	264	OWN	Report No. 103845
850.1075	Fish toxicity - bluegill	42055314	264	OWN	Report No. 100348
850.1075	Fish toxicity rainbow trout	42055315	264	OWN	Report No. 100349
850.1075	Fish toxicity rainbow trout	42055316	264	OWN	Report No. 101303
850.1400	Early life stage - fish	42055320	264	OWN	Report No. 101214
850.1400	Early life stage - fish	42480501	264	OWN	Report No. 101214-1
850.1500	Life cycle invertebrate	42055321	264	OWN	Report No. 100247 (Daphnia)

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



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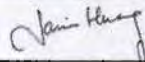
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.1500	Life cycle invertebrate	42055322	264	OWN	Report No. 101347 (mysid)
850.1950	Simulated or actual field study	42256306	264	OWN	Report No. 102600
850.2100	Acute avian oral	42055308	264	OWN	Report No. 100059 (Bobwhite quail)
850.2100	Acute avian oral	43310401	264	OWN	Report No. 106608 (Japanese quail)
850.2100	Acute avian oral	43310403	264	OWN	Report No. 106610 (canary)
850.2100	Acute avian oral	43310404	264	OWN	Report No. 106611 (pigeon)
850.2100	Acute avian oral	44059401	264	OWN	Report No. 107354 (mallard duck)
850.2100	Acute avian oral	44457401	264	OWN	Report No.107904 (Japanese quail)
850.2200	Avian dietary - quail	42055310	264	OWN	Report No. 100241 (Bobwhite quail)
850.2200	Avian dietary - quail	43310402	264	OWN	Report No. 106609 (Japanese quail)
850.2200	Avian dietary - duck	42055311	264	OWN	Report No. 100238
850.2300	Avian reproduction - quail	42055312	264	OWN	Report No. 101203
850.2300	Avian reproduction - duck	42055313	264	OWN	Report No. 101205
850.2300	Avian reproduction - duck	42480502	264	OWN	Report No. 103813
850.2300	Avian reproduction - duck	42805101	264	OWN	Report No. 103813-1

Signature



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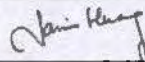
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.2300	Avian reproduction - duck	43466501	264	OWN	Report No. 106623
850.2300	Avian reproduction - duck	43466502	264	OWN	Report No. 106630
850.2500	Simulated or actual field study	42737101	264	OWN	Report No. 105002
850 None	Foliar half-life and distribution for potatoes	42556101	264	OWN	Report No. 103233
850 None	Runoff and Erosion predictions for apple/potato/cotton	42556102	264	OWN	Report No. 103809
850 None	Risk assessment for apple/potato/cotton	42556103	264	OWN	Report No. 103900
850 None	PELMO Modeling - sugarbeet/Germany	42734102	264	OWN	Report No. 105008
<b>Non-Target Insects, Section 158.590</b>					
850.3020	Honey bee acute contact	42273003	264	OWN	Report No. 101321
850.3020	Honey bee acute contact	42480503	264	OWN	Report No. 103815
850.3030	Honey bee residue on foliage	42480503	264	OWN	Report No. 103815
850.3030	Honey bee residue on foliage	42632901	264	OWN	Report No. 103938
<b>Plant Protection, Section 158.540</b>					

Signature



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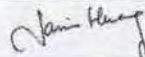
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.4400	Aquatic plant growth	42256374	264	OWN	Report No. 100098 (Scenedesmus)
850.4400	Aquatic plant growth	42256375	264	OWN	Report No. 101986 (Selenastrum)
850.4400	Aquatic plant growth	44187112	264	OWN	Report No. 107549 (Anabaena)
850.4400	Aquatic plant growth	44187102	264	OWN	Report No. 107658 (Navicula)
<b>Residue, Section 158.240</b>					
860.1300	Nature of residue - plants	42556105	264	OWN	Report No. 103818 (cotton)
860.1300	Nature of residue - plants	42556106	264	OWN	Report No. 103218 (potato)
860.1300	Nature of residue - plants	42556107	264	OWN	Report No. 103211 (potato)
860.1300	Nature of residue - plants	42556108	264	OWN	Report No. 103216 (apples)
860.1300	Nature of residue - plants	42556109	264	OWN	Report No. 103212 (tomatoes)
860.1300	Nature of residue - plants	42556110	264	OWN	Report No. 103210 (eggplant)
860.1300	Nature of residue - plants	42556111	264	OWN	Report No. 103217 (corn)
860.1300	Nature of residue - plants	42556112	264	OWN	Report No. 103213
860.1300	Nature of residue - plants	42556113	264	OWN	Report No. 103902
860.1300	Nature of residue - plants	43143201	264	OWN	Report No.103818-1 (cotton)

Signature



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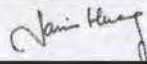
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1300	Nature of residue - plants	43715501	264	OWN	Report No. 106631 (tobacco)
860.1300	Nature of residue - livestock and poultry	42556114	264	OWN	Report No. 103819 (goat)
860.1300	Nature of residue - livestock and poultry	42556115	264	OWN	Report No.103819-1 (goat)
860.1300	Nature of residue - livestock and poultry	42556116	264	OWN	Report No. 102607 (hen)
860.1300	Nature of residue - livestock and poultry	42556117	264	OWN	Report No.102607-1 (hen)
860.1300	Nature of residue - livestock and poultry	43126901	264	OWN	Report No. 102607 (hen)
860.1340	Residue analytical method - plants	42556118	264	OWN	Report No. 102624R
860.1340	Residue analytical method - plants	42556120	264	OWN	Report No. 103828
860.1340	Residue analytical method - plants	43143202	264	OWN	Report No. 102624R-1
860.1340	Residue analytical method - plants	43143208	264	OWN	Report No. 106427
860.1340	Residue analytical method - animal	42556119	264	OWN	Report No. 103848R
860.1340	Residue analytical method - animal	42556120	264	OWN	Report No. 103828

Signature



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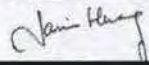
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1340	Residue analytical method - animal	43143203	264	OWN	Report No. 103848R-1
860.1340	Residue analytical method - animal	43143208	264	OWN	Report No. 106427
860.1360	Method validation/ multiresidue method	42556121	264	OWN	Report No. 99632
860.1360	Method validation/ multiresidue method	42556122	264	OWN	Report No. 103840
860.1360	Method validation/ multiresidue method	42556123	264	OWN	Report No. 103214
860.1360	Method validation/ multiresidue method	42556124	264	OWN	Report No. 103214-1
860.1360	Method validation/ multiresidue method	42556125	264	OWN	Report No. 103827
860.1360	Method validation/ multiresidue method	42556126	264	OWN	Report No. 103829
860.1360	Method validation/ multiresidue method	42556127	264	OWN	Report No. 103830
860.1360	Method validation/ multiresidue method	42556128	264	OWN	Report No. 103244

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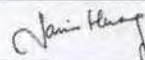
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1360	Method validation/ multiresidue method	43143204	264	OWN	Report No. 106418
860.1360	Method validation/ multiresidue method	43143205	264	OWN	Report No. 106425
860.1360	Method validation/ multiresidue method	43337201	264	OWN	Report No. 106781
860.1360	Method validation/ multiresidue method	43463001	264	OWN	Report No. 106781-1
860.1360	Method validation/ multiresidue method	43551504	264	OWN	Report No. 106900
860.1360	Method validation/ multiresidue method	43581301	264	OWN	Report No. 106782
860.1360	Method validation/ multiresidue method	45051401	IR-4	PER	Project No. 45815
860.1380	Storage stability	42556135	264	OWN	Report No. 103237
860.1380	Storage stability	42556136	264	OWN	Report No. 103820
860.1380	Storage stability	42556137	264	OWN	Report No. 103831
860.1380	Storage stability	42556138	264	OWN	Report No. 103847

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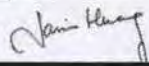
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1380	Storage stability	42810311	264	OWN	Report No. 103237-1
860.1380	Storage stability	42810312	264	OWN	Report No. 103949
860.1380	Storage stability	42810313	264	OWN	Report No. 103949-1
860.1380	Storage stability	43197201	264	OWN	Report No. 103949-2
860.1380	Storage stability	43197202	264	OWN	Report No. 103820-1
860.1380	Storage stability	43197203	264	OWN	Report No. 103237-2
860.1380	Storage stability	43487301	264	OWN	Report No. 102634
860.1380	Storage stability	43487302	264	OWN	Report No. 103237-3
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556139	264	OWN	Report No. 103833 (cattle)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556140	264	OWN	Report No. 103832 (poultry)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556141	264	OWN	Report No. 103834 (poultry)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556142	264	OWN	Report No. 103836 (transfer)
860.1480	Magnitude of residues -	42810314	264	OWN	Report No. 103836-1 (transfer)

Signature



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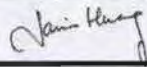
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	meat/milk/poultry/egg				
860.1480	Magnitude of residues - meat/milk/poultry/egg	43143206	264	OWN	Report No. 103833-1 (cattle)
860.1480	Magnitude of residues - meat/milk/poultry/egg	43143207	264	OWN	Report No. 103832-1 (poultry)
860.1500	Magnitude of residue - crop field trials	42556129	264	OWN	Report No. 103824 (cotton)
860.1500	Magnitude of residue - crop field trials	42556131	264	OWN	Report No. 103235 (potato)
860.1500	Magnitude of residue - crop field trials	42556133	264	OWN	Report No. 103234 (apples)
860.1500	Magnitude of residue - crop field trials	42767801	264	OWN	Report No. 103234-1 (apples)
860.1500	Magnitude of residue - crop field trials	42767802	264	OWN	Report No. 103824-1 (cotton)
860.1500	Magnitude of residue - crop field trials	42810301	264	OWN	Report No. 105015 (tomato)
860.1500	Magnitude of residue - crop field trials	42810302	264	OWN	Report No. 103245 (grape)

Signature



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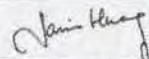
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	42810303	264	OWN	Report No. 103245-1 (grape)
860.1500	Magnitude of residue - crop field trials	42810304	264	OWN	Report No. 105019 (broccoli)
860.1500	Magnitude of residue - crop field trials	42810305	264	OWN	Report No. 105022 (cauliflower)
860.1500	Magnitude of residue - crop field trials	42810306	264	OWN	Report No. 105040 (cabbage)
860.1500	Magnitude of residue - crop field trials	42810307	264	OWN	Report No. 105164 (lettuce)
860.1500	Magnitude of residue - crop field trials	4281308	264	OWN	Report No. 105165 (Brassica vegetables)
860.1500	Magnitude of residue - crop field trials	42881001	264	OWN	Report No. 105016 (pepper)
860.1500	Magnitude of residue - crop field trials	42995701	264	OWN	Report No. 105011 (mango)
860.1500	Magnitude of residue - crop field trials	43398901	IR-4	PER	Project No. 5369 (hops)
860.1500	Magnitude of residue - crop field trials	43551501	264	OWN	Report No. 106437 (citrus)

Signature



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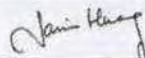
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Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	43551503	264	OWN	Report No. 106777 (pecan)
860.1500	Magnitude of residue - crop field trials	43600001	264	OWN	Report No. 103824-2 (cotton)
860.1500	Magnitude of residue - crop field trials	43675101	264	OWN	Report No. 106631-1 (tobacco)
860.1500	Magnitude of residue - crop field trials	43801101	264	OWN	Report No. 106789 (pear)
860.1500	Magnitude of residue - crop field trials	43970401	264	OWN	Report No. 103842 (tobacco)
860.1500	Magnitude of residue - crop field trials	44067501	IR-4	PER	Project No. 5181 (cucumber)
860.1500	Magnitude of residue - crop field trials	44067502	IR-4	PER	Project No. 5180 (melon)
860.1500	Magnitude of residue - crop field trials	44067503	IR-4	PER	Project No. 5179 (squash)
860.1500	Magnitude of residue - crop field trials	44067504	IR-4	PER	Project No. A5181 (cucumber)

Signature



Name and Title:

Jamin Huang, Registration Manager

Date: September 15, 2008



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
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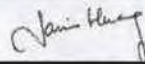
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	44067505	IR-4	PER	Project No. A5180 (melon)
860.1500	Magnitude of residue - crop field trials	44067506	IR-4	PER	Project No. A5179 (squash)
860.1500	Magnitude of residue - crop field trials	44213101	264	OWN	Report No. 107563 (spinach)
860.1500	Magnitude of residue - crop field trials	44438101	264	OWN	Report No. 107126 (celery))
860.1500	Magnitude of residue - crop field trials	44438102	264	OWN	Report No. 106662 (citrus)
860.1500	Magnitude of residue - crop field trials	44438103	264	OWN	Report No. 106662-1 (citrus)
860.1500	Magnitude of residue - crop field trials	44438104	264	OWN	Report No. 106437-1 (citrus)
860.1500	Magnitude of residue - crop field trials	44524901	IR-4	PER	Project No. 95-004 (squash)
860.1500	Magnitude of residue - crop field trials	44524902	IR-4	PER	Project No. 95-007 (cucumber)
860.1500	Magnitude of residue - crop field trials	44524903	IR-4	PER	Project No. 95-006 (cantaloupe)

Signature



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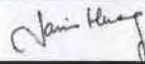
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	44815601	264	OWN	Report No. 108805 (grape)
860.1500	Magnitude of residue - crop field trials	44951601	264	OWN	Report No. 108731 (banana)
860.1500	Magnitude of residue - crop field trials	44982301	264	OWN	Report No. 108847 (potato)
860.1500	Magnitude of residue - crop field trials	45036801	IR-4	PER	Project No. 05477 (succulent beans)
860.1500	Magnitude of residue - crop field trials	45046401	IR-4	PER	Project No. 0620.95-MD03 (lima beans)
860.1500	Magnitude of residue - crop field trials	45194301	IR-4	PER	Project No. 05745 (cranberry)
860.1500	Magnitude of residue - crop field trials	45228401	IR-4	PER	Project No. 0622.97-CA62 (artichoke)
860.1500	Magnitude of residue - crop field trials	45349501	IR-4	PER	Project No. 06307 (carrot)
860.1500	Magnitude of residue - crop field trials	45433801	264	OWN	Report No. 110753 (cucumber)

Signature



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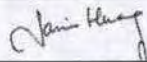
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	45433802	264	OWN	Report No. 110754 (cucumber, tomato, pepper))
860.1500	Magnitude of residue - crop field trials	45433803	264	OWN	Report No. 110755 (cucumber)
860.1500	Magnitude of residue - crop field trials	45433804	264	OWN	Report No. 110756 (tomato)
860.1500	Magnitude of residue - crop field trials	45433805	264	OWN	Report No. 110757 (cucumber)
860.1500	Magnitude of residue - crop field trials	45433806	264	OWN	Report No. 110758 (tomato)
860.1500	Magnitude of residue - crop field trials	45433807	264	OWN	Report No. 110759 (pepper)
860.1500	Magnitude of residue - crop field trials	45547001	IR-4	PER	Project No. 06449 (passion fruit)
860.1500	Magnitude of residue - crop field trials	45580401	IR-4	PER	Project No. 06398 (pea)
860.1500	Magnitude of residue - crop field trials	45587101	IR-4	PER	Project No. 06450 (mamey sapote)
860.1500	Magnitude of residue - crop field trials	45597901	IR-4	PER	Project No. 06305 (garden beet)

Signature



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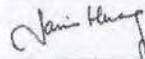
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	45616301	IR-4	PER	Project No. 06260 (strawberry)
860.1500	Magnitude of residue - crop field trials	45616401	IR-4	PER	Project No. 06528 (dry bean)
860.1500	Magnitude of residue - crop field trials	45619701	IR-4	PER	Project No. 06399 (cherry)
860.1500	Magnitude of residue - crop field trials	45619702	IR-4	PER	Project No. 06399 (peach)
860.1500	Magnitude of residue - crop field trials	45619703	264	OWN	Report No. 109238 (peach)
860.1500	Magnitude of residue - crop field trials	45619704	IR-4	PER	Project No. 07279 (plum)
860.1500	Magnitude of residue - crop field trials	45647801	IR-4	PER	Project No. 07738 (guava)
860.1500	Magnitude of residue - crop field trials	45757801	IR-4	PER	Project No. 06308( Radish)
860.1500	Magnitude of residue - crop field trials	45795701	IR-4	PER	Project No. 07351 (papaya)

Signature



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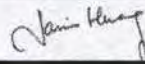
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	45795701	IR-4	PER	Project No. A07351 (papaya)
860.1500	Magnitude of residue - crop field trials	45826301	IR-4	PER	Project No. A07523 (raspberry)
860.1500	Magnitude of residue - crop field trials	46025801	IR-4	PER	Project No. 97/001 (sunflower)
860.1500	Magnitude of residue - crop field trials	46031401	IR-4	PER	Project No. A06993 (sugar apple)
860.1500	Magnitude of residue - crop field trials	46188201	IR-4	PER	Project No. 07099 (avocado)
860.1520	Processing Study	42556130	264	OWN	Report No. 103246 (cotton)
860.1520	Processing Study	42556132	264	OWN	Report No. 103238 (potato)
860.1520	Processing Study	42556134	264	OWN	Report No. 103236 (apples)
860.1520	Processing Study	42767803	264	OWN	Report No. 103246-1 (cotton)
860.1520	Processing Study	42810309	264	OWN	Report No. 105024 (tomato)
860.1520	Processing Study	42810310	264	OWN	Report No. 103839 (grape)
860.1520	Processing Study	43490301	264	OWN	Report No. 106651 (tomato)

Signature



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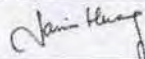
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1520	Processing Study	43551502	264	OWN	Report No. 106771 (orange)
860.1520	Processing Study	44438105	264	OWN	Report No. 106771-1 (orange)
860.1520	Processing Study	46025801	IR-4	PER	Project No. 97/001 (sunflower)
860.1850	Confined rotational crop	42556104	264	OWN	Report No. 103812
860.1900	Field rotational crop	43245901	264	OWN	Report No. 105153
860.1900	Field rotational crop	44063701	264	OWN	Report No. 107133
<b>Toxicology, Section 158.340</b>					
870.1100	Acute oral toxicity rat	42055331	264	OWN	Report No. 100040 (TGAI)
870.1100	Acute oral toxicity rat	42256313	264	OWN	Report No. 100010 (2 F)
870.1100	Acute oral toxicity rat	43428201	264	OWN	Report No. 106380 (1.6 F)
870.1200	Acute dermal toxicity, rat/rabbit	42055332	264	OWN	Report No. 100041 (TGAI)
870.1200	Acute dermal toxicity, rat/rabbit	42256315	264	OWN	Report No. 100002 (2 F)
870.1200	Acute dermal toxicity, rat/rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.1300	Acute inhalation toxicity, rat	42055333	264	OWN	Report No. 99806 (TGAI)
870.1300	Acute inhalation toxicity, rat	42286101	264	OWN	Report No. 99806-1 (TGAI)

Signature



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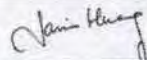
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.1300	Acute inhalation toxicity, rat	42256317	264	OWN	Report No. 100012 (2 F)
870.1300	Acute inhalation toxicity, rat	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2400	Primary eye irritation - rabbit	42055334	264	OWN	Report No. 99679 (TGAI)
870.2400	Primary eye irritation - rabbit	42256319	264	OWN	Report No. 99815 (2 F)
870.2400	Primary eye irritation - rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2500	Primary dermal irritation - rabbit	42055335	264	OWN	Report No. 99804 (TGAI)
870.2500	Primary dermal irritation - rabbit	42256321	264	OWN	Report No. 99816 (2 F)
870.2500	Primary dermal irritation - rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2600	Dermal sensitization - guinea pig	42055336	264	OWN	Report No. 99800 (TGAI)
870.2600	Dermal sensitization - guinea pig	42256323	264	OWN	Report No. 100003 (2 F)
870.2600	Dermal sensitization - guinea pig	43428201	264	OWN	Report No. 106380 (1.6 F)
870.3100	90-day feeding - rodent	42256327	264	OWN	Report No. 100036
870.3150	90-day feeding - non-rodent	42256328	264	OWN	Report No. 100176
870.3200	21-day dermal - rabbit/rat	42256329	264	OWN	Report No. 100688
870.3700	Developmental toxicity - rat	42256338	264	OWN	Report No. 98571

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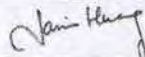
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.3700	Developmental toxicity - rabbit	42256339	264	OWN	Report No. 98572
870.3800	Two generation reproduction - rat	42256340	264	OWN	Report No. 100647
870.4100	Chronic feeding toxicity - rodent	42256331	264	OWN	Report No. 100652
870.4100	Chronic feeding toxicity - rodent	42256332	264	OWN	Report No. 101931
870.4100	Chronic feeding toxicity - rodent	42256333	264	OWN	Report No. 102658
870.4100	Chronic feeding toxicity - rodent	42256334	264	OWN	Report No. 99672
870.4100	Chronic feeding toxicity - non-rodent	42273002	264	OWN	Report No. 100015
870.4200	Oncogenicity - rat	42256331	264	OWN	Report No. 100652
870.4200	Oncogenicity - rat	42256332	264	OWN	Report No. 101931
870.4200	Oncogenicity - rat	42256333	264	OWN	Report No. 102658
870.4200	Oncogenicity - rat	42256334	264	OWN	Report No. 99672
870.4200	Oncogenicity - rat	42256335	264	OWN	Report No. 100693
870.4200	Oncogenicity - rat	42256336	264	OWN	Report No. 101929
870.4200	Oncogenicity - rat	42256337	264	OWN	Report No. 99808
870.5100	Gene mutation (ames test)	42256341	264	OWN	Report No. 101276

Signature



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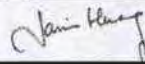
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.5100	Gene mutation (ames test)	42256342	264	OWN	Report No. 98584
870.5100	Gene mutation (ames test)	42256343	264	OWN	Report No. 98570
870.5375	Structural chromosomal aberration	42256344	264	OWN	Report No. 100021
870.5375	Structural chromosomal aberration	42256345	264	OWN	Report No. 99262
870.5375	Structural chromosomal aberration	42256346	264	OWN	Report No. 99257
870.5375	Structural chromosomal aberration	42256347	264	OWN	Report No. 102652
870.5375	Structural chromosomal aberration	42256348	264	OWN	Report No. 102654
870.5375	Structural chromosomal aberration	42256349	264	OWN	Report No. 102655
870.5395	Micronucleus test	42256350	264	OWN	Report No. 99676
870.5395	Micronucleus test	42256351	264	OWN	Report No. 101275
870.5550	Unscheduled DNA synthesis	42256352	264	OWN	Report No. 98573
870.5550	Unscheduled DNA synthesis	42256353	264	OWN	Report No. 102653
870.6200	Acute neurotoxicity	43170301	264	OWN	Report No. 106348
870.6200	Acute neurotoxicity	43285801	264	OWN	Report No. 106348-1
870.6200	90 day neurotoxicity - mammal	43286401	264	OWN	Report No. 106356

Signature



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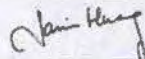
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.6300	Developmental neurotoxicity	45537501	264	OWN	Report no. 110245
870.7485	General metabolism	42256354	264	OWN	Report No. 101999
870.7485	General metabolism	42256355	264	OWN	Report No. 87264
870.7485	General metabolism	42256356	264	OWN	Report No. 87265
870.7485	General metabolism	42256357	264	OWN	Report No. 102617
<b>Reentry Protection, Section 158.390</b>					
875 Group A and B	Mixer/loader/applicator exposure	42256386	264	OWN	Report No. 94273
875.2100	Foliar dislodgeable exposure	44957601	264	OWN	Report No. 109318
<b>Spray Drift, Section 158.440</b>					
201-1	Droplet size spectrum	43766502	SDTF	PER	Report No. A92/004
<b>Applicator Exposure</b>					
None	Worker Exposure study	42256386	264	OWN	Report No. 94273
<b>Miscellaneous Supplemental Studies</b>					
None	Benefits Reports	42620801	264	OWN	Report No. 103881
None	Benefits Reports	42810315	264	OWN	Report No. 103878

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;  
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DATA MATRIX

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

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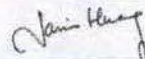
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

None	Dietary Analysis	44790101	264	OWN	Report No. 108790
None	Dietary Analysis	44886001	264	OWN	Report No. 109180
None	Dietary Analysis	44886002	264	OWN	Report No. 109180-1

Signature



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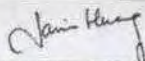
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Sepresto 75 WS					
			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	
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			Bayer Cropscience	OWN	

Signature



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**DATA MATRIX**

Date: September 15, 2008	EPA Reg. No./File Symbol: 264-RNIR	Page 2 of 2
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid		

	Bayer Cropscience	OWN
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	Bayer Cropscience	OWN

Signature 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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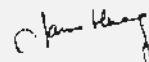
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

Bayer Cropscience	OWN
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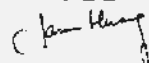
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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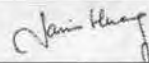
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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Product(s):  
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Ingredient: Clothianidin + Imidacloprid

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Imidacloprid			
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	264	OWN	

Signature



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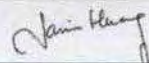
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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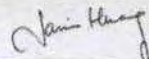
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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### DATA MATRIX

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Product(s):  
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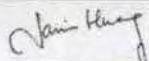
Bayer CropScience, 2 T.W. Alexander Drive  
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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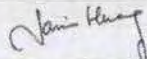
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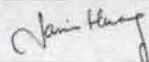
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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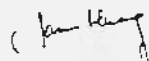
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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Applicant=s/Registrant=s Name & Address:

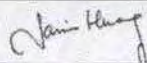
Bayer CropScience, 2 T.W. Alexander Drive  
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**DATA MATRIX**

Date: September 15, 2008	EPA Reg. No./File Symbol: 264-RNIR	Page 14 of 14
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA		Product(s): Sepresto 75 WS
Ingredient: Clothianidin + Imidacloprid		

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Signature: 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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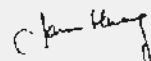
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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USA

Product(s):  
Seprasto 75 WS

Ingredient: Clothianidin + Imidacloprid

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Date: September 15, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 16 of 16

Applicant=s/Registrant=s Name & Address:

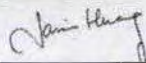
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
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264	OWN

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



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**DATA MATRIX**

Date: September 15, 2008	EPA Reg. No./File Symbol: 264-RNIR	Page 17 of 17
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid		

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	264	OWN

Signature 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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**DATA MATRIX**

Date: September 15, 2008

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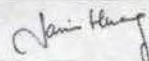
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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Signature



Name and Title:  
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Date: September 15, 2008



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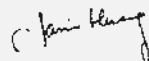
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
 RTP, NC 27709  
 USA

Product(s):  
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Ingredient: Clothianidin + Imidacloprid

264	OWN
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Signature



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**DATA MATRIX**

Date: September 15, 2008		EPA Reg. No./File Symbol: 264-RNIR	Page 20 of 20
Applicant/s/Registrant/s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA		Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid			

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Signature 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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EPA Reg. No./File Symbol: 264-RNIR

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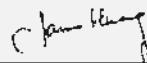
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	IR-4	PER	
	264	OWN	
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	264	OWN	
	264	OWN	
	IR-4	PER	
	IR-4	PER	
	IR-4	PER	
	IR-4	PER	

Signature



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Page 22 of 22

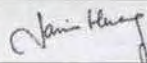
Applicant=s/Registrant=s Name & Address: **Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA**

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	IR-4	PER
	IR-4	PER
	IR-4	PER
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	264	OWN
	264	OWN
	264	OWN
	264	OWN
	IR-4	PER

Signature



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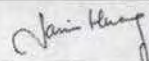
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
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IR-4	PER

Signature



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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid		

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IR-4	PER	

Signature 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid		

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Page 26 of 28

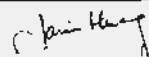
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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Signature



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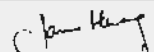
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Applicant/s/Registrant/s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS
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Ingredient: Clothianidin + Imidacloprid

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Signature: 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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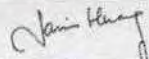
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA		Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid			

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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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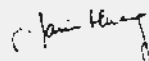
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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SDTF	PER
264	OWN

Signature



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Applicant/s/Registrant/s Name & Address:

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RTP, NC 27709  
USA

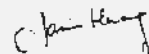
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
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264	OWN

Signature



Name and Title:

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Date: September 15, 2008



**E-SUBMISSION**

**Fee for Service**

{835821!~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr.

Receipt No.

S-

EPA File Symbol/Reg. No.

Pin-Punch Date:

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: RR

Date: 9-15-08

Remarks: Additional data for an earlier e-submission from Bayer.

**E-SUBMISSION**





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 22, 2008

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

MARGARET CHERNY  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE  
RESEARCH TRIANGLE PARK, NC 27709

PRODUCT NAME: Sepresto 75 WS  
COMPANY NAME: BAYER CROPSCIENCE LP  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 264-RNIR  
EPA RECEIPT DATE: 09/18/08

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Registration Division, Risk Management Team 1, at (703) 308-8045.

Sincerely,

A handwritten signature in cursive script, appearing to read "Y. H. Moore".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



# E-SUBMISSION

**Fee for Service**

*[Signature]*  
{836442\$~

This package includes the following

- ☐ New Registration
- ☒ Amendment

- ☐ Studies?      ☐ Fee Waiver?
- ☐ volpay    % Reduction: \_\_\_\_

for Division

- ☐ AD
- ☐ BPPD
- ☒ RD

Risk Mgr. 1

Receipt No.

S-

836442

EPA File Symbol/Reg. No.

264-RNIR

Pin-Punch Date:

9/18/2008



This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ \_\_\_\_

Parent/Child Decisions:

☒ Inert Cleared for Intended Use

☐ Uncleared Inert in Product

Reviewer: *RA*

Date: *9-22-08*

Remarks: *Resubmissions*

# E-SUBMISSION



## Memorandum

submission

Date: 9 / 15 / 08

To: PM 01, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

**We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.**

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission  
☐ partially accepted submission  
☐ rejected submission



All corrected  
9/17/08

Food use

PRIA 2 - 21 Day Content Screen Review Worksheet

(EPA/OPP Use Only)

21 Day Screen Start Date: 8/20/08  
Experts In-Processing Signature: [Signature] Date 9/5/08 Fee Paid: Yes ☒  
Division management contacted on issues No ☐ Yes ☐ Date           

EPA Reg. Number: <u>264-KNIR</u>		EPA Receipt Date: <u>8/20/08</u>				
Items for Review			Yes	No	N/A*	
1	<b>Application Form</b> (EPA Form 8570-1) signed & complete including package type <u>missing Section III information. Registrant says they have determined the packaging and container information yet.</u>			<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<u>corrected 9/17/08</u>
2	<b>Confidential Statement of Formula</b> all boxes completed, form signed, and dated (EPA Form 8570-4)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	a) All inerts, except fragrances, approved for food and non food proposed uses (see Footnote A)	yes	no			
		<input checked="" type="checkbox"/>	<input type="checkbox"/>			
3	<b>Certification with Respect to Citation of Data</b> (EPA Form 8570-34) completed and signed (N/A if 100% repack)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
	Certificate and data matrix consistent <u>data matrix needs correction</u>			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>corrected 9/17/08</u>
	If applicant is relying on data that are compensable, is the offer to pay statement included. (see Footnote B)	yes	no			
		<input type="checkbox"/>	<input type="checkbox"/>			
	If applicable, is there a letter of Authorization for exclusive use only.			<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
4	<b>Formulator's Exemption Statement</b> (EPA Form 8570-27) completed and signed (N/A if source is unregistered or applicant owns the technical)			<input type="checkbox"/>	<input checked="" type="checkbox"/>	<u>corrected 9/17/08</u>
	<b>Data Matrix</b> (EPA Form 8570-35) both internal and external copies (PR 98-5) completed and signed (N/A if 100% repack) *			<input checked="" type="checkbox"/>	<input type="checkbox"/>	
5	a) Selective Method (Fee category experts use)	yes	no			
		<input checked="" type="checkbox"/>	<input type="checkbox"/>			
	b) Cite-All (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
	c) Applicant owns all data (Fee category experts use)	<input type="checkbox"/>	<input type="checkbox"/>			
6	<b>5 Copies of Label</b> (Electronic labels on CD are encouraged) <u>e-submission</u>			<input type="checkbox"/>	<input type="checkbox"/>	
7	Is the data package consistent with PR Notice 86-5 <u>Failed first time Second time - OK</u>			<input checked="" type="checkbox"/>	<input type="checkbox"/>	<u>corrected 9/17/08</u>
8	<b>Notice of Filing</b> (link to included with petitions)			<input checked="" type="checkbox"/>	<input type="checkbox"/>	

\* Note: Dr. Huang said he submitted Agency Internal Copy re-submission. PM team will need to get public file copy out of Documentum.



9	If applicable for conventional applications, reduced risk rationale			✓
10	Required Data and/or data waivers. See Footnote C.			
	a) List study (or studies) not included with application			

Comments:

(FES)

Formulators Exemption Statement: You cannot claim a formulator's exemption for your own product (264-755). Submit new FES for [REDACTED] only.

Data matrix: Revise data matrix to list all <sup>imidacloprid</sup> data necessary to support registration of 264-RNIR and list all ~~new~~ new use data for clothianidin. Since you are purchasing a registered [REDACTED] from another source, you do not need to list that data.

Application Form: I have discussed this item with other screeners and we agree that you must submit a complete application Form, Section III. It is unacceptable to submit an application without this information.

\*Product ingredient source information may be entitled to confidential treatment\*

\* N/A – Not Applicable



## Footnotes

A. This consideration does not apply to PRIA applications that include a request to approve an inert in the fee category. For these PRIA actions, information needs to be submitted to enable the Agency to review the inert approval request and will be a subject of the 21 day content screen. For other types of actions and for fragrances, the answer is only for the Agency's information and current policies, processes, and procedures should be consulted. This worksheet will be updated in the future to be consistent with current policies.

If brand, trade, or proprietary names are being used for some inert ingredients listed on the CSF, alternate names or additional information on the nature of the ingredient(s) should be provided to allow the Agency to determine whether the inert has been approved.

B. A policy on documentation of offers to pay is still being developed, however, for a me-too or fast track (similar/identical) new product, R300 or A530, an application without the necessary authorizations of offers to pay will be placed into either R301 or A531. The Agency recommends that authorizations of offers to pay be submitted with other PRIA applications to avoid delays in the Agency's decision.

C. Refer to the list of data requirements. Biopesticide applicants were advised to contact the Agency and discuss study waivers prior to submitting their application to the Agency. Documentation of such discussions should be submitted with the study waiver.



Bayer CropScience



September 16, 2008 (via e-mail)

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD), Ms. Linda Arrington (Team Leader, N&MF), Ms. Mary Waller (PM 21, RD)

**Re: Response to 21 Day Content Screen Review Worksheet**

**Sepresto 75 WS (EPA File Symbol: 264-RNIR)**

Dear Ms. Waller,

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Bayer CropScience is herein submitting the following requested documents as listed in the PRIA 2 – 21 Day Content Screen Review Worksheet (attached)

- (1) Revised Form 8570-1 to include packaging and container information in Section III
- (2) Revised data matrix for both Agency and Public Use copies to include the reports for imidacloprid
- (3) Revised Form 8570-27

Please contact me at 919-549-2634 or at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) if you have any questions regarding this submission.

Sincerely,

Jamin Huang  
Product Registration Manager

Attachments





United States  
Environmental Protection Agency  
Washington, DC 20480

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 264-XXXX	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sepresto 75 WS	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer Cropscience 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address	6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____	

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

REGFEE: PRIA II R310 (to register a new end-use product, Sepresto 75 WS, \$ 4,360. Request for a 15 month (instead of 6 month) review to be in sync with other PRIA actions for Sepresto 75 WS

JUSTIFICATIONS: As one of the 6 PRIA II actions to register a new product, Sepresto 75 WS, for seed treatment uses on a number of new crops. Please see the enclosed cover letter for details.

CONTACT: Jamin Huang e-mail address: jamin.huang@bayercropscience.com

## Section - III

1. Material This Product Will Be Packaged in:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input type="checkbox"/> Metal	revised 9/15/08 JH
				<input type="checkbox"/> Plastic	
				<input type="checkbox"/> Glass	
* Certification must be submitted				<input type="checkbox"/> Paper	
	If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container	<input checked="" type="checkbox"/> Other (Specify) fiber
3. Location of Net Contents Information <input checked="" type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container 5 lb and 25 lb		5. Location of Label Directions <input checked="" type="checkbox"/> ON CONTAINER inside	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper, glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)				
Name Jamin Huang, Ph.D.		Title Registration Product Manager		
		Telephone No. (Include Area Code) 919-549-2634		
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.			6. Date Application Received (Stamped)	
2. Signature 		3. Title Registration Product Manager		
4. Typed Name Jamin Huang, Ph.D.		5. Date August 1, 2008		





United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	EPA File Symbol/Registration Number 264-RNIR
	Product Name Sepresto 75 WS
	Date of Confidential Statement of Formula (EPA Form 8570-4) 08/01/2008

As an authorized representative of the applicant for registration of the product identified above, I certify that:

(1) This product contains the following active ingredient(s):

clothianidin and imidacloprid

(2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

(3) Indicate by checking (A) or (B) below which paragraph applies:

☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement.

That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

☐ (B) The Confidential Statement of Formula (CSF) (EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

(4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Clothianidin		
*Product ingredient source information may be entitled to confidential treatment*		
Signature	Name and Title Jamin Huang, Registration Manager	Date 09/11/2008

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy





UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 3, 2008

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

OPP Decision Number: D-399489  
EPA File Symbol or Registration Number: 264-RNIR  
Product Name: Sepresto 75 WS  
EPA Receipt Date: 20-Aug-2008  
EPA Company Number: 264  
Company Name: BAYER CROPSCIENCE LP

MARGARET CHERNY  
BAYER CROPSCIENCE LP  
2 T.W. ALEXANDER DRIVE  
RESEARCH TRIANGLE PARK, NC 27709

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application and certification of payment. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: R310

NEW PRODUCT;NON-FAST TRACK (INCLUDES REVIEWS OF PRODUCT  
CHEMISTRY;ACUTE TOXICITY;PUBLIC HEALTH PEST EFFICACY);

No additional payment is due at this time.

If you have any questions, please contact the Pesticide Registration Service Fee  
Ombudsman at (703) 305-6249.

Sincerely,

A handwritten signature in cursive script, appearing to read "Teresa Downs", is written over a horizontal line.

Front End Processing Staff  
Information Technology & Resources Management Division



E-Sub # 1040

**Fee for Service**

{834686R~

This package includes the following

☒ New Registration

☐ Amendment

☒ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: \_\_\_\_

for Division

☐ AD

☐ BPPD

☒ RD

Risk Mgr. 1

Receipt No.

S- 834686

EPA File Symbol/Reg. No.

264-RNIR

Pin-Punch Date:

8/20/2008

☐ This item is NOT subject to FFS action.

Action Code:

Requested: R310

Granted: R310

Amount Due: \$ 4360.00

Parent/Child Decisions:

~~X~~ Inert Cleared for Intended Use

Inert's approved. A. Debesen 9/10/08

Uncleared Inert in Product

Reviewer: Mary Waller

Date: 8/25/2008

Remarks: Registrant requested 15 month completion time to allow for tolerance action to be completed.

Sepresto - negotiated date for 15 mo.



BAY MELLON, N.A.  
PITTSBURGH PA 15262



Bayer  
Pittsburgh, PA 15262

CHECK NO. 3100004386

60-160

433

PAY:

\*\*\*FOUR THOUSAND THREE HUNDRED SIXTY  
AND 00/100 DOLLARS\*\*\*

VOID 180 DAYS AFTER DATE OF CHECK

DATE: 08-01-08 \$\*\*\*\*\*4,360.00

TO  
THE  
ORDER  
OF

ENVIRONMENTAL PROTECTION AGENCY  
USEPA WASHINGTON FINANCE CENTER  
PESTICIDE REGISTRATION SERVICE  
PO BOX 979074  
ST. LOUIS MO 63197-9000  
Ca # 264 Sepresto R310

Authorized Signatures

*Mary E. Spagnoli*  
*Can S. Bak*

"3100004386"



Bayer  
Pittsburgh, PA 15262

U1P/110 BEGBV

VENDOR NO.	VENDOR NAME	DATE	CHECK NO.	CHECK AMOUNT	
6768799	Environmental Protection Agency	08-01-08	3100004386	4,360.00	
REFERENCE NO.	DATE	DOCUMENT NO	GROSS AMOUNT	DISCOUNT	NET AMOUNT
06TIP007JHF	07-28-08	2401265859	4,360.00	0.00	4,360.00
Sepresto R310					





United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 264-XXXX	2. EPA Product Manager Venus Eagle	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) Sepresto 75 WS	PM# 01	
5. Name and Address of Applicant (Include ZIP Code) Bayer Cropscience 2 T.W. Alexander Drive Research Triangle Park, NC 27709 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

## Section - II

<input type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input checked="" type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

REGFEE: PRIA II R310 (to register a new end-use product, Sepresto 75 WS, \$ 4,360. Request for a 15 month (instead of 6 month) review to be in sync with other PRIA actions for Sepresto 75 WS

JUSTIFICATIONS: As one of the 6 PRIA II actions to register a new product, Sepresto 75 WS, for seed treatment uses on a number of new crops. Please see the enclosed cover letter for details.

CONTACT: Jamin Huang e-mail address: jamin.huang@bayercropscience.com

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No	<input type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____		
* Certification must be submitted		If "Yes" Unit Packaging wgt.	No. per container	If "Yes" Package wgt	No. per container
3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container		4. Size(s) Retail Container		5. Location of Label Directions <input type="checkbox"/> ON CONTAINER	
6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled		<input type="checkbox"/> Other _____			

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)					
Name Jamin Huang, Ph.D.		Title Registration Product Manager		Telephone No. (Include Area Code) 919-549-2634	
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.					
2. Signature 		3. Title Registration Product Manager		6. Date Application Received (Stamped)  251	
4. Typed Name Jamin Huang, Ph.D.		5. Date August 1, 2008			



Bayer CropScience



August 1, 2008

Document Processing Desk (REGFEE)  
Office of Pesticide Programs (7505P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, Virginia 22202-4501

Attention: Ms. Venus Eagle (PM 01, RD)

**Re: Registration Application of a New End-Use Product: Proceed  
Optimum (EPA Reg. No. 264-XXXX) for Seed Treatment Use on  
Wheat, Barley and Triticale**

**As a Secondary PRIA Action to the Sepresto 75 WS Submission**

Bayer CropScience  
2 T.W. Alexander Drive  
P. O. Box 12014  
Research Triangle Park,  
NC 27709  
Tel: 919 549-2000

Dear Ms. Eagle,

Bayer CropScience is herein submitting a registration application for a new end-use product, **Proceed Optimum**. Since it is one of the Secondary PRIA actions to be linked to the registration application of Sepresto 75 WS (as the Primary PRIA action), per your instructions, it is being submitted under PRIA R190.2 action. We request an extension of the decision time for this PRIA action to 15 months to be in sync with that of the Sepresto 75 WS application.

Proceed Optimum contains clothianidin (1.46%), prothioconazole (1.46%), tebuconazole (0.29%) and metalaxyl (0.59%) for seed treatment use on wheat, barley and triticale. The proposed use rates for the three fungicides, prothioconazole, tebuconazole and metalaxyl, in Proceed Optimum are equal to their rates for the same use in the pending registration application for Proceed MD Fungicide (EPA File Symbol. 264-RNTE, OPP Decision No.: D-386008, with PRIA due date of Feb. 19, 2009). The proposed use on wheat, barley and triticale for clothianidin in Proceed Optimum is supported by the data from the Sepresto 75 WS registration application (as the Primary PRIA action).

Proceed Optimum is coded as "L1829 end-use product" in the product chemistry brochure, and as "Proceed w CTD" in the six acute toxicity reports.



M-305140-01-1

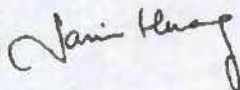


The following documents are included in the enclosed CD to support this application:

- (1) Application for Pesticide Amendment (EPA Form 8570-1) dated August 1, 2008. REGFEE: PRIA II R190.2 with a fee of \$ 81,600. A copy of our check of \$ 81,600 in payment of the PRIA II fee. We request a discretionary refund for what the Agency has reviewed for the pending Proceed MD (EPA File Symbol. 264-RNTE, OPP Decision No.: D-386008).
- (2) Transmittal document dated August 1, 2008
- (3) An electronic file of the proposed labeling of Proceed Optimum dated August 1, 2008 and a certification with respect to label integrity dated August 1, 2008
- (4) An electronic file of the proposed Confidential Statement of Formula (CSF) for Proceed Optimum dated June 23, 2008, and justifications for the selection of certified limits for certain inert ingredients
- (5) EPA Form 8570-27 dated August 1, 2008 – for clothianidin, prothioconazole, tebuconazole and metalaxyl.
- (6) EPA Form 8570-34 dated August 1, 2008
- (7) An electronic file of the "Agency Internal Use copy" of Proceed Optimum data matrix signed and dated August 1, 2008
- (8) An electronic file of the "Public File copy" of the corresponding Proceed Optimum data matrix, signed and dated August 1, 2008
- (9) An electronic copy of all of the study reports listed in Transmittal Document in support of this application.

Please contact me at 919-549-2634 or at [jamin.huang@bayercropscience.com](mailto:jamin.huang@bayercropscience.com) if you have any questions regarding this submission.

Sincerely,



Jamin Huang, Ph.D.  
Product Registration Manager

Attachments



## TRANSMITTAL DOCUMENT

1. Name and Address of Submitter:

Bayer CropScience  
2 T.W. Alexander Drive  
PO Box 12014  
Research Triangle Park, NC 27709

Jamin Huang, Ph.D.  
Registration Product Manager  
Regulatory Affairs  
919-549-2634

2. Regulatory Action(s) in Support of Which This Data is Being Submitted:

Submission of a new end-use product, **PROCEED Optimum**, which contains clothianidin (1.46%), prothioconazole (1.46%), tebuconazole (0.29%) and metalaxyl (0.59%) for seed treatment use on wheat, barley and triticale, as one of the Secondary PRIA actions linked to the registration application of Sepresto 75WS (as the Primary PRIA action). The proposed use rates for prothioconazole, tebuconazole and metalaxyl in PROCEED Optimum are equal to the rates for the same use in the pending registration application for PROCEED MD Fungicide (EPA File Symbol. 264-RNTE, OPP Decision No. D-386008). The proposed rate for clothianidin in PROCEED Optimum is supported by the data from the Sepresto 75WS registration application (as the Primary PRIA action).

3. Transmittal Date:

August 1, 2008

4. List of Submitted Studies:MRID NO.Study Report

47483301

1. "The Physical Characterization of L1829 End-Use Product" (OPPTS Guidelines Series 830 and 40 CFR 158)



M-305193-01-1

1



- |          |   |
|----------|---|
| 47483302 | 2. "The Method of Enforcement Validation of L1829 End-Use Product" (OPPTS 830.1800)   |
| 47483303 | 3. "Proceed w CTD - Acute Oral Toxicity Up and Down Procedure in Rats" (OPPTS 870.1100) [Report No. 24806]                                      |
| 47483304 | 4. "Proceed w CTD - Acute Dermal Toxicity Study in Rats - Limit Test" (OPPTS 870.1200) [Report No. 24807]                                       |
| 47483305 | 5. "Proceed w CTD - Acute Inhalation Toxicity Study in Rats - Limit Test" (OPPTS 870.1300) [Report No. 24808]                                   |
| 47483306 | 6. "Proceed w CTD - Primary Eye Irritation Study in Rabbits" (OPPTS 870.2400) [Report No. 24809]  |
| 47483307 | 7. "Proceed w CTD - Primary Skin Irritation Study in Rabbits" (OPPTS 870.2500) [Report No. 24810]   |
| 47483308 | 8. "Proceed w CTD - Dermal Sensitization Study in Guinea Pigs (Buehler Method)" (OPPTS 870.2600) [Report No. 24811]                             |
| 47483309 | 9. "Assessment of Worker Exposure and Risk Resulting from On-Farm and Commercial Treatment of Wheat, Barley and Triticale with Proceed Optimum" |





Document Title

**Document A**

**Statement of the context in which the dossier is submitted for**

**Sepresto 75 WS**

Data Requirements

**Regulatory Directive 2003-01/Canada/PMRA**

**OPPTS guidelines/US/EPA**

**According to OECD format guidance for industry data submissions  
on plant protection products and their active substances**

Date

**August 1, 2008**

Authors

**Jamin Huang  
Bayer CropScience  
Research Triangle Park, NC, USA**

**Roy Lidstone  
Bayer CropScience Inc.  
Ottawa, Ontario, Canada**

Number of pages

**3**



### **Statement of the context in which the dossier is submitted**

Bayer CropScience is submitting an application to register a new seed treatment insecticide product called Sepresto 75 WS to both the United States Environmental Protection Agency and the Canadian Pest Management Regulatory Agency as a North America Second-Entry Joint Review. Sepresto 75 WS is a seed treatment insecticide intended for use on vegetable and cereal seeds.

Sepresto 75 WS contains the active ingredients clothianidin and imidacloprid. Clothianidin and several end-use seed treatment products containing clothianidin – Poncho, Prosper, Titan – have been registered by both the EPA and PMRA since 2003. They were assessed and registered in a North America Joint Review as OP replacements. As seed treatments, clothianidin is registered for use on corn and canola in both countries, and on cotton, sugar beets and sorghum in the US only. Corresponding tolerances or maximum residue limits (MRLs) for clothianidin have been established for corn and canola in both countries.

Imidacloprid has been registered in both the US and Canada for more than ten years and is utilized as an active ingredient in several products including Admire, Provado and Gaucho. Imidacloprid is registered on many crops and can be applied directly to the soil, as a foliar spray and as a seed treatment to control insects.

Sepresto 75 WS is intended for use as a seed treatment product for Crop group 1 Root and Tuber vegetables, Crop group 3 Bulb vegetables, Crop sub-group 4A Leafy green vegetables, Crop group 5 Brassica vegetables, Crop group 8 Fruiting vegetables and Crop group 9 Cucurbit vegetables in both the US and Canada. In the US only, potatoes, Crop group 15 Cereal grain without rice and Crop group 16 Forage, fodder and straw of Cereal Grains without rice are also on the proposed Sepresto 75 WS label.

In addition to requesting registration of the proposed uses in both the US and in Canada, Bayer CropScience is requesting the establishment of MRLs or tolerances for food commodities grown from the treated seeds. The proposed MRLs are supported by 1) the residue reports needed to establish clothianidin tolerances for all of these crop groups, 2) the residue report required to establish imidacloprid tolerances for Crop group 3 Bulb vegetables, and 3) the use of the existing and proposed imidacloprid tolerances for the other crops (via foliar and soil applications) to register the proposed seed treatment uses on the same crop groups.

The registration application package for Sepresto 75 WS also includes a new clothianidin rotational crop residue study report for matured soybean to support our proposed potato seed piece treatment at the 420 g ai/ha rate. The environmental load for clothianidin for the proposed uses is estimated to be lower than the 0.4 lbs/acre (= 448 g ai/ha) rate currently registered for the use of clothianidin on turf in the US. Similarly, the environmental load for imidacloprid for the proposed uses is below the rates currently registered.

In the US, there will be two companion applications (as Secondary PRIA actions) to be linked to the Sepresto 75 WS application (the Primary PRIA action) – 1) addition of Crop Group 3 Bulb vegetables to Gaucho 550 SC (a registered product in the US, EPA Reg. No. 264-827), and 2)



Proceed Optimum, as a new product similar to pending Proceed MD (EPA File Symbol 264-RNTE, Decision No. D-386008), for seed treatment use on wheat, barley and triticale.

In the US, imidacloprid-containing products have been registered for uses on all of the crops listed in the Sepresto 75 WS labeling, with the only exception of Crop group 3 Bulb vegetables. A residue program conducted for onions was based on soil application, and its data will be used to support soil application *via* Gaucho 550 SC (EPA Reg. No. 264-827), as a Secondary PRIA action as noted above, and seed treatment use *via* Sepresto 75WS. The existing imidacloprid tolerances already established for all of the other crops are based on foliar and soil uses, and will be used to register the proposed seed treatment uses on the same crop groups. A number of imidacloprid seed treatment uses have been previously approved by the Agency based on their foliar and/or soil applied uses.

In Canada, the application to register Sepresto 75 WS is being accompanied by an application to amend the registration of Admire 240 Flowable Systemic Insecticide, Registration number 24094, by adding uses previously registered in the US, i.e., "Technology Gap" approach. The new uses proposed for the Canadian Admire 240 F label have been registered in the US on the Provado and Admire labels registered by Bayer CropScience. The reason for the submission is to provide Canadian growers with the same imidacloprid products and uses available to growers in the US. Bayer CropScience is requesting that the PMRA establish MRLs that are harmonized with existing US tolerances in order to facilitate trade of imidacloprid-treated food commodities.

The registration of the new uses proposed for the Admire 240 F label in Canada and the concurrent establishment of crop and crop group MRLs, will also serve as the basis for the imidacloprid MRLs required for Sepresto 75 WS in Canada.



Bayer CropScience



**TRANSMITTAL DOCUMENT**

**Clothianidin**

**Sepresto 75 WS (Joint CAN&US)**

**Transmittal Date**  
August 01, 2008

A handwritten signature in black ink, appearing to read "Jamin Huang".

Company Official:

Company Name: Bayer Cropscience

Company Contact: Jamin Huang

Company Telephone: +1 919 549 2634

2 T.W. Alexander Drive  
RTP, NC 27709  
USA



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<b>830 Series Product Properties</b>			
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United States  
Environmental Protection Agency  
Washington, DC 20460  
**Formulator's Exemption Statement**  
(40 CFR 152.85)

Applicant's Name and Address Bayer CropScience 2 T.W. Alexander Drive Research Triangle Park, NC 27709	EPA File Symbol/Registration Number 264-XXXX
	Product Name Sepresto 75 WS
	Date of Confidential Statement of Formula (EPA Form 8570-4) 08/01/2008

As an authorized representative of the applicant for registration of the product identified above, I certify that:

- (1) This product contains the following active ingredient(s):

clothianidin and imidacloprid

- (2) Of these, each active ingredient listed in paragraph (4) is present solely as the result of the use of that active ingredient in the manufacturing, formulation or repackaging another product which contains that active ingredient which is registered under FIFRA Section 3, is purchased by us from another person and meets the requirements of 40 CFR section 158.50(e)(2) or (3).

- (3) Indicate by checking (A) or (B) below which paragraph applies:

- ☒ (A) An accurate Confidential Statement of Formula (EPA FORM 8570-4) for the above identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the active ingredient(s) listed in paragraph (1).

OR

- ☐ (B) The Confidential Statement of Formula (CSF)(EPA Form 8570-4) referenced above and on file with the EPA is complete, current, an accurate and contains the information required on the current CSF.

- (4) The following active ingredients in this product qualify for the formulator's exemption.

Source		
Active Ingredient	Product Name	Registration Number
Clothianidin		
Imidacloprid	NTN 33893 Technical	264-755
*Product ingredient source information may be entitled to confidential treatment*		
Signature 	Name and Title Jamin Huang, Registration Manager	Date 08/01/2008

EPA Form 8570-27 (Rev. 06-2004)

Copy 1 - EPA  
Copy 2 - Applicant copy



M-305211-01-1





**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**Certification with Respect to Citation of Data**

Applicant's/Registrant's Name, Address, and Telephone Number Bayer CropScience, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709 (919-549-2634)	EPA Registration Number/File Symbol 264-XXXX
Active Ingredient(s) and/or representative test compound(s) clothianidin and imidacloprid	Date August 1, 2008
General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Seed Treatment, Terrestrial Food Use	Product Name Sepresto 75 WS

**NOTE:** If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

**SECTION I: METHOD OF DATA SUPPORT (Check one method only)**

☐ I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

☒ I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used).

**SECTION II: GENERAL OFFER TO PAY**

(Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements)

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

**SECTION III: CERTIFICATION**

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature 	Date 08/01/08	Typed or Printed Name and Title Jamin Huang, Product Registration Manager
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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for Reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

**DATA MATRIX**

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 1 of 1

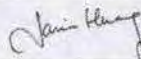
Applicant=s/Registrant=s Name & Address: **Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA**

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
<b>Sepresto 75 WS</b>					
830.1550	Product Identity and Composition	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1600	Description of Material Used to Produce the Product	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1620	Decription of Product Process	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1650	Decription of Formulation Process	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1670	Discussion of Formation of Impurities	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1700	Preliminary Analysis	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1750	Certified Limits	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.1800	Enforcement Analytical Method	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6302	Color	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6303	Physical State	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6304	Odor	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6317	Storage Stability	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.6320	Corrosion Characteristics	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
**WASHINGTON, D.C. 20460**

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**DATA MATRIX**

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

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Applicant=s/Registrant=s Name & Address:

Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

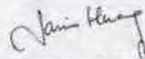
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.7000	pH of Water Solutions or Suspensions	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
830.7300	Density/Relative Density/Bulk Density	47483001	Bayer Cropscience	OWN	M-304667-01-1 (BR 2645)
835.1240	Soil Column Leaching	47483002	Bayer Cropscience	OWN	M-270224-02-1 (METIX050-1)
835.2120	Hydrolysis of Parent and Degradates as a Function of pH at 25 C	47483003	Bayer Cropscience	OWN	M-267329-02-1 (METIX051-1)
850.1735	Whole Sediment: Acute Freshwater Invertebrates	46826902	Bayer Cropscience	OWN	M-271041-01-1 (EBTIX063)
850.1950	Field Testing for Aquatic Organisms	47483004	Bayer Cropscience	OWN	M-044250-01-2 (DECO 082)
860.1300	Analytical Method	47483005	Bayer Cropscience	OWN	M-278059-01-1 (NT-001-P04-01)
830.1300	Validation report	47483006	Bayer Cropscience	OWN	M-289314-01-1 (RATY008) Lynx Number: RATY008
860.1300	Independent Laboratory Validation	47483007	Bayer Cropscience	OWN	M-283049-01-1 (RATY018)
860.1300	Outside Laboratory Validation	42556124	Bayer Cropscience	OWN	M-003302-01-1 (103214)
860.1300	Clothiadin Multiresidue Method	47483008	Bayer Cropscience	OWN	M-272961-01-1 (RATY016)
860.1300	Imidacloprid Multiresidue Method	42556122	Bayer Cropscience	OWN	M-020722-01-2 (103840)
860.1380	Storage Stability Data	47483009	Bayer Cropscience	OWN	M-303705-01-1 (RATY015) Lynx Number: RATY015

Signature



Name and Title:

Jamin Huang, Registration Manager

Date: September 15, 2008



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Applicant=s/Registrant=s Name & Address:

Bayer CropScience, 2 T.W. Alexander Drive  
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USA

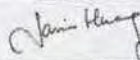
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1380	Storage Stability Data	43487301~~	Bayer Cropscience	OWN	M-090224-01-2 (103949-3)
860.1380	Storage Stability Data	47483010	Bayer Cropscience	OWN	M-090199-01-2 (103949-4)
860.1380	Storage Stability Data	43197203~~ 47483011	Bayer Cropscience	OWN	M-090164-01-1 (103237-2)
860.1500	Potatoes	47483012	Bayer Cropscience	OWN	M-282086-01-1 (RATY004)
860.1500	Potatoes	47483013	Bayer Cropscience	OWN	M-304969-01-1 (AAFC04-001 R)
860.1500	Root Vegetables	47483014	Bayer Cropscience	OWN	M-304701-01-1 (RATIP043) Lynx Number: RATIP043
860.1500	Bulb Vegetables	47483015	Bayer Cropscience	OWN	M-304371-01-1 (RATIP044) Lynx Number: RATIP044
860.1500	Bulb Vegetables	47483016	Bayer Cropscience	OWN	M-304592-01-1 (RATY020) Lynx Number: RATY020
860.1500	Leafy Greens	47483017	Bayer Cropscience	OWN	M-304730-01-1 (RATIL001) Lynx Number: RATIL001
860.1500	Brassica Leafy Vegetables	47483018	Bayer Cropscience	OWN	M-304704-01-1 (RATIL002) Lynx Number: RATIL002
860.1500	Fruiting Vegetables	47483019	Bayer Cropscience	OWN	M-304551-01-1 (RATIP046) Lynx Number: RATIP046
860.1500	Cucurbit Vegetables	47483020	Bayer Cropscience	OWN	M-300700-01-1 (RATIP045)

Signature



Name and Title:

Jamin Huang, Registration Manager

Date: September 15, 2008



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Bayer CropScience, 2 T.W. Alexander Drive  
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USA

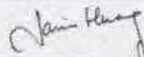
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

					Lynx Number: RATIP045
860.1500	Wheat	47483021	Bayer Cropscience	OWN	M-303764-01-1 (RATY013) Lynx Number: RATY013
860.1520	Potato Processed Commodities	47483022	Bayer Cropscience	OWN	M-282378-01-1 (RATY005)
860.1520	Tomato Processed Commodities	47483023	Bayer Cropscience	OWN	M-304478-01-1 (RATIP041) Lynx Number: RATIP041
860.1520	Wheat Processed Commodities	47483024	Bayer Cropscience	OWN	M-304174-01-1 (RATIP037) Lynx Number: RATIP037
860.1900	Soybeans (Rotational Crop)	47496202	Bayer Cropscience	OWN	M-304695-01-1 (RATY011) Lynx Number: RATFP001
870.1100	Acute Oral Toxicity	47483025	Bayer Cropscience	OWN	M-301714-01-1 (24696) Lynx Number: TXTIP001
870.1200	Acute Dermal Toxicity	47483026	Bayer Cropscience	OWN	M-292803-01-2 (AT04102) Lynx Number: TXTIX111
870.1300	Acute Inhalation Toxicity	47483027	Bayer Cropscience	OWN	M-294053-01-2 (AT04206) Lynx Number: TXTIX122
870.2400	Acute Eye Irritation	47483028	Bayer Cropscience	OWN	M-292824-01-2 (AT04106) Lynx Number: TXTIX112
870.2500	Acute Dermal Irritation	47483029	Bayer Cropscience	OWN	M-292823-01-2 (AT04107) Lynx Number: TXTIX113

Signature



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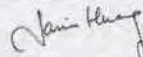
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.2600	Skin Sensitization	47483030	Bayer Cropscience	OWN	M-293656-01-2 (AT04180) Lynx Number: TXTIX114
875.1100	Dermal Exposure--Outdoor	47483031	Bayer Cropscience	OWN	M-043846-01-2 (MR-565/01)
875.1100	Dermal Exposure--Outdoor	47483032	Bayer Cropscience	OWN	M-305114-01-1 (G201919)
875.1300	Inhalation Exposure--Outdoor	47483031	Bayer Cropscience	OWN	M-043846-01-2 (MR-565/01)
875.1300	Inhalation Exposure--Outdoor	47483032	Bayer Cropscience	OWN	M-305114-01-1 (G201919)
SUPP	Groundwater Exposure Assessment	47483033	Bayer Cropscience	OWN	M-304828-01-1 (RAT1Y024) Lynx Number: RAT1Y024
SUPP	Acute and Chronic Dietary Exposure Assessment	47483034	Bayer Cropscience	OWN	M-305112-01-1 (G201914)
SUPP	Assessment of worker exposure (Canada)	47483035	Bayer Cropscience	OWN	M-305586-01-1 (G201925)
<b>Imidacloprid</b>					
830.1550	Chemical identity	42055302	264	OWN	BR 1759 (TGAI)
830.1550	Chemical identity	43306001	264	OWN	BR 1879 (TGAI)
830.1550	Chemical identity	42256302	264	OWN	BR 1766 (Formulation)
830.1600	Statement of Composition	42055302	264	OWN	BR 1759 (TGAI)

Signature



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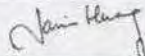
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.1600	Statement of Composition	42270801	264	OWN	BR 1785 (TGAI)
830.1600	Statement of Composition	43306001	264	OWN	BR 1879 (TGAI)
830.1600	Statement of Composition	42256302	264	OWN	BR 1766 (Formulation)
830.1670	Formation of impurities	42055302	264	OWN	BR 1759 (TGAI)
830.1670	Formation of impurities	42256302	264	OWN	BR 1766 (Formulation)
830.1700	Preliminary analysis	42055303	264	OWN	BR 1760 (TGAI)
830.1700	Preliminary analysis	42270802	264	OWN	BR 1786 (TGAI)
830.1700	Preliminary analysis	43306002	264	OWN	BR 1880 (TGAI)
830.1700	Preliminary analysis	42256302	264	OWN	BR 1766 (Formulation)
830.1750	Certification of limits	42055303	264	OWN	BR 1760 (TGAI)
830.1750	Certification of limits	43306002	264	OWN	BR 1880 (TGAI)
830.1750	Certification of limits	42256302	264	OWN	BR 1766 (Formulation)
830.1800	Analytical method	42055303	264	OWN	BR 1760 (TGAI)
830.1800	Analytical method	43213001	264	OWN	BR 1874 (TGAI)
830.1800	Analytical method	43306002	264	OWN	BR 1880 (TGAI)

Signature



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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.1800	Analytical method	42256302	264	OWN	BR 1766 (Formulation)
830.6301	Chemical and Physical Properties	42055304	264	OWN	BR 1761 (TGAI)
830.6301	Chemical and Physical Properties	42256302	264	OWN	BR 1766 (Formulation)
830.6302	Appearance	42055304	264	OWN	BR 1761 (TGAI)
830.6302	Appearance	42256302	264	OWN	BR 1766 (Formulation)
830.6303	Physical state	42055304	264	OWN	BR 1761 (TGAI)
830.6303	Physical state	42256302	264	OWN	BR 1766 (Formulation)
830.6304	Odor	42055304	264	OWN	BR 1761 (TGAI)
830.6304	Odor	42256302	264	OWN	BR 1766 (Formulation)
830.6313	Stability	42055304	264	OWN	BR 1761 (TGAI)
830.6315	Flammability	42055304	264	OWN	BR 1761 (TGAI)
830.6316	Explodability	42055304	264	OWN	BR 1761 (TGAI)
830.6317	Storage stability	42055304	264	OWN	BR 1761 (TGAI)
830.6317	Storage stability	42256302	264	OWN	BR 1766 (Formulation)
830.6320	Corrosion characteristics	42055304	264	OWN	BR 1761 (TGAI)

Signature



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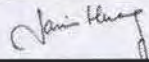
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

830.6320	Corrosion characteristics	42256302	264	OWN	BR 1766 (Formulation)
830.7000	pH	42055304	264	OWN	BR 1761 (TGAI)
830.7000	pH	42256302	264	OWN	BR 1766 (Formulation)
830.7200	Melting point	42055304	264	OWN	BR 1761 (TGAI)
830.7220	Boiling point	42055304	264	OWN	BR 1761(TGAI)
830.7300	Density	42055304	264	OWN	BR 1761 (TGAI)
830.7300	Density	43356302	264	OWN	BR 1761 (Formulation)
830.7560	Octanol / water partition	42055304	264	OWN	BR 1761 (TGAI)
830.7840	Solubility	42055304	264	OWN	BR 1761 (TGAI)
830.7950	Vapor pressure	42055304	264	OWN	BR 1761 (TGAI)
<b>Environmental Fate, Section 158.290</b>					
835.1230	Leaching / adsorption/desorption	42055338	264	OWN	Report No. 99199
835.1230	Leaching / adsorption/desorption	42055339	264	OWN	Report No. 99635
835.1230	Leaching / adsorption/desorption	42520801	264	OWN	Report No. 103816
835.1230	Leaching / adsorption/desorption	42520802	264	OWN	Report No. 103817

Signature



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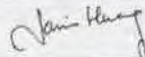
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

835.2120	Hydrolysis	42055337	264	OWN	Report No. 99708
835.2240	Photodegradation - water	42256376	264	OWN	Report No. 101956
835.2410	Photodegradation - soil	42256377	264	OWN	Report No. 100249
835.4100	Aerobic soil metabolism	42539201	264	OWN	Report No. 100140
835.4100	Aerobic soil metabolism	42539202	264	OWN	Report No. 100141
835.4100	Aerobic soil metabolism	42539203	264	OWN	Report No. 101955
835.4100	Aerobic soil metabolism	42539204	264	OWN	Report No. 103202
835.4100	Aerobic soil metabolism	45239301	264	OWN	Report No. PF 3321
835.4100	Aerobic soil metabolism	45239302	264	OWN	Report No. PF 3322
835.4200	Anerobic soil metabolism	42073501	264	OWN	Report No. 101241
835.4400	Anaerobic aquatic metabolism	42256378	264	OWN	Report No. 101346
835.6100	Terrestrial field dissipation	42256379	264	OWN	Report No. 101987
835.6100	Terrestrial field dissipation	42256380	264	OWN	Report No. 101988
835.6100	Terrestrial field dissipation	42256381	264	OWN	Report No. 101989
835.6100	Terrestrial field dissipation	42256382	264	OWN	Report No. 102603

Signature



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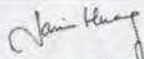
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

835.6100	Terrestrial field dissipation	42256383	264	OWN	Report No. 102604
835.6100	Terrestrial field dissipation	42256384	264	OWN	Report No. 101984
835.6100	Terrestrial field dissipation	42256385	264	OWN	Report No. 101981
835.6100	Terrestrial field dissipation	42734101	264	OWN	Report No. 103948
835.7100	Ground water - small prospective	43142501	264	OWN	Report No. 106426
835.7100	Ground water - small prospective	43315201	264	OWN	Report No.106426-1
835.7100	Ground water - small prospective	43449501	264	OWN	Report No. 106637
835.7100	Ground water - small prospective	44790102	264	OWN	Report No. 108791
835.7100	Ground water - small prospective	44790103	264	OWN	Report No. 108792
835.7100	Ground water - small prospective	45094701	264	OWN	Report No. 109383
835.7100	Ground water - small prospective	45094702	264	OWN	Report No. 109596
835.7100	Ground water - small prospective	45094703	264	OWN	Report No. 108939
835.7100	Ground water - small prospective	45858201	264	OWN	Report No. 110773
835.7100	Ground water - small prospective	45878701	264	OWN	Report No. 110889
835 None	Environmental fate summary	42734103	264	OWN	Report No. 105010

Signature



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Date: September 15, 2008



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**DATA MATRIX**

Date: September 15, 2008

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Applicant=s/Registrant=s Name & Address:

Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

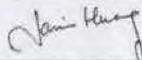
Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

**Wildlife and Aquatic Organisms,  
Section 158.490**

850.1010	Invertebrate toxicity - Daphnia	42055317	264	OWN	Report No. 100245
850.1010	Invertebrate toxicity - Amphipods	42256303	264	OWN	Report No. 101960
850.1010	Acute aquatic invertebrate toxicity - Chironomids	42256304	264	OWN	Report No. 101985
850.1025	Estuarine / marine toxicity - fish	42055318	264	OWN	Report No. 100354
850.1025	Estuarine / marine toxicity - mollusk	42256305	264	OWN	Report No. 101978
850.1025	Estuarine/marine toxicity - shrimp	42055319	264	OWN	Report No. 100355
850.1025	Estuarine/marine toxicity - shrimp	42528301	264	OWN	Report No. 103845
850.1075	Fish toxicity - bluegill	42055314	264	OWN	Report No. 100348
850.1075	Fish toxicity rainbow trout	42055315	264	OWN	Report No. 100349
850.1075	Fish toxicity rainbow trout	42055316	264	OWN	Report No. 101303
850.1400	Early life stage - fish	42055320	264	OWN	Report No. 101214
850.1400	Early life stage - fish	42480501	264	OWN	Report No. 101214-1
850.1500	Life cycle invertebrate	42055321	264	OWN	Report No. 100247 (Daphnia)

Signature



Name and Title:

Jamin Huang, Registration Manager

Date: September 15, 2008



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**1200 Pennsylvania Avenue, N.W.**  
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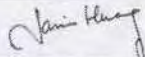
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.1500	Life cycle invertebrate	42055322	264	OWN	Report No. 101347 (mysid)
850.1950	Simulated or actual field study	42256306	264	OWN	Report No. 102600
850.2100	Acute avian oral	42055308	264	OWN	Report No. 100059 (Bobwhite quail)
850.2100	Acute avian oral	43310401	264	OWN	Report No. 106608 (Japanese quail)
850.2100	Acute avian oral	43310403	264	OWN	Report No. 106610 (canary)
850.2100	Acute avian oral	43310404	264	OWN	Report No. 106611 (pigeon)
850.2100	Acute avian oral	44059401	264	OWN	Report No. 107354 (mallard duck)
850.2100	Acute avian oral	44457401	264	OWN	Report No.107904 (Japanese quail)
850.2200	Avian dietary - quail	42055310	264	OWN	Report No. 100241 (Bobwhite quail)
850.2200	Avian dietary - quail	43310402	264	OWN	Report No. 106609 (Japanese quail)
850.2200	Avian dietary - duck	42055311	264	OWN	Report No. 100238
850.2300	Avian reproduction - quail	42055312	264	OWN	Report No. 101203
850.2300	Avian reproduction - duck	42055313	264	OWN	Report No. 101205
850.2300	Avian.reproduction - duck	42480502	264	OWN	Report No. 103813
850.2300	Avian reproduction - duck	42805101	264	OWN	Report No. 103813-1

Signature



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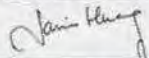
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.2300	Avian reproduction - duck	43466501	264	OWN	Report No. 106623
850.2300	Avian reproduction - duck	43466502	264	OWN	Report No. 106630
850.2500	Simulated or actual field study	42737101	264	OWN	Report No. 105002
850 None	Foliar half-life and distribution for potatoes	42556101	264	OWN	Report No. 103233
850 None	Runoff and Erosion predictions for apple/potato/cotton	42556102	264	OWN	Report No. 103809
850 None	Risk assessment for apple/potato/cotton	42556103	264	OWN	Report No. 103900
850 None	PELMO Modeling - sugarbeet/Germany	42734102	264	OWN	Report No. 105008
<b>Non-Target Insects, Section 158.590</b>					
850.3020	Honey bee acute contact	42273003	264	OWN	Report No. 101321
850.3020	Honey bee acute contact	42480503	264	OWN	Report No. 103815
850.3030	Honey bee residue on foliage	42480503	264	OWN	Report No. 103815
850.3030	Honey bee residue on foliage	42632901	264	OWN	Report No. 103938
<b>Plant Protection, Section 158.540</b>					

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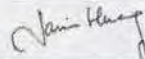
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

850.4400	Aquatic plant growth	42256374	264	OWN	Report No. 100098 (Scenedesmus)
850.4400	Aquatic plant growth	42256375	264	OWN	Report No. 101986 (Selenastrum)
850.4400	Aquatic plant growth	44187112	264	OWN	Report No. 107549 (Anabaena)
850.4400	Aquatic plant growth	44187102	264	OWN	Report No. 107658 (Navicula)
<b>Residue, Section 158.240</b>					
860.1300	Nature of residue - plants	42556105	264	OWN	Report No. 103818 (cotton)
860.1300	Nature of residue - plants	42556106	264	OWN	Report No. 103218 (potato)
860.1300	Nature of residue - plants	42556107	264	OWN	Report No. 103211 (potato)
860.1300	Nature of residue - plants	42556108	264	OWN	Report No. 103216 (apples)
860.1300	Nature of residue - plants	42556109	264	OWN	Report No. 103212 (tomatoes)
860.1300	Nature of residue - plants	42556110	264	OWN	Report No. 103210 (eggplant)
860.1300	Nature of residue - plants	42556111	264	OWN	Report No. 103217 (corn)
860.1300	Nature of residue - plants	42556112	264	OWN	Report No. 103213
860.1300	Nature of residue - plants	42556113	264	OWN	Report No. 103902
860.1300	Nature of residue - plants	43143201	264	OWN	Report No.103818-1 (cotton)

Signature



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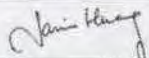
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1300	Nature of residue - plants	43715501	264	OWN	Report No. 106631 (tobacco)
860.1300	Nature of residue - livestock and poultry	42556114	264	OWN	Report No. 103819 (goat)
860.1300	Nature of residue - livestock and poultry	42556115	264	OWN	Report No.103819-1 (goat)
860.1300	Nature of residue - livestock and poultry	42556116	264	OWN	Report No. 102607 (hen)
860.1300	Nature of residue - livestock and poultry	42556117	264	OWN	Report No.102607-1 (hen)
860.1300	Nature of residue - livestock and poultry	43126901	264	OWN	Report No. 102607 (hen)
860.1340	Residue analytical method - plants	42556118	264	OWN	Report No. 102624R
860.1340	Residue analytical method - plants	42556120	264	OWN	Report No. 103828
860.1340	Residue analytical method - plants	43143202	264	OWN	Report No. 102624R-1
860.1340	Residue analytical method - plants	43143208	264	OWN	Report No. 106427
860.1340	Residue analytical method - animal	42556119	264	OWN	Report No. 103848R
860.1340	Residue analytical method - animal	42556120	264	OWN	Report No. 103828

Signature



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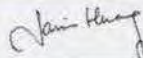
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1340	Residue analytical method - animal	43143203	264	OWN	Report No. 103848R-1
860.1340	Residue analytical method - animal	43143208	264	OWN	Report No. 106427
860.1360	Method validation/ multiresidue method	42556121	264	OWN	Report No. 99632
860.1360	Method validation/ multiresidue method	42556122	264	OWN	Report No. 103840
860.1360	Method validation/ multiresidue method	42556123	264	OWN	Report No. 103214
860.1360	Method validation/ multiresidue method	42556124	264	OWN	Report No. 103214-1
860.1360	Method validation/ multiresidue method	42556125	264	OWN	Report No. 103827
860.1360	Method validation/ multiresidue method	42556126	264	OWN	Report No. 103829
860.1360	Method validation/ multiresidue method	42556127	264	OWN	Report No. 103830
860.1360	Method validation/ multiresidue method	42556128	264	OWN	Report No. 103244

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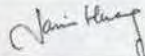
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1360	Method validation/ multiresidue method	43143204	264	OWN	Report No. 106418
860.1360	Method validation/ multiresidue method	43143205	264	OWN	Report No. 106425
860.1360	Method validation/ multiresidue method	43337201	264	OWN	Report No. 106781
860.1360	Method validation/ multiresidue method	43463001	264	OWN	Report No. 106781-1
860.1360	Method validation/ multiresidue method	43551504	264	OWN	Report No. 106900
860.1360	Method validation/ multiresidue method	43581301	264	OWN	Report No. 106782
860.1360	Method validation/ multiresidue method	45051401	IR-4	PER	Project No. 45815
860.1380	Storage stability	42556135	264	OWN	Report No. 103237
860.1380	Storage stability	42556136	264	OWN	Report No. 103820
860.1380	Storage stability	42556137	264	OWN	Report No. 103831
860.1380	Storage stability	42556138	264	OWN	Report No. 103847

Signature



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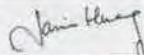
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1380	Storage stability	42810311	264	OWN	Report No. 103237-1
860.1380	Storage stability	42810312	264	OWN	Report No. 103949
860.1380	Storage stability	42810313	264	OWN	Report No. 103949-1
860.1380	Storage stability	43197201	264	OWN	Report No. 103949-2
860.1380	Storage stability	43197202	264	OWN	Report No. 103820-1
860.1380	Storage stability	43197203	264	OWN	Report No. 103237-2
860.1380	Storage stability	43487301	264	OWN	Report No. 102634
860.1380	Storage stability	43487302	264	OWN	Report No. 103237-3
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556139	264	OWN	Report No. 103833 (cattle)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556140	264	OWN	Report No. 103832 (poultry)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556141	264	OWN	Report No. 103834 (poultry)
860.1480	Magnitude of residues meat/milk/poultry/egg -	42556142	264	OWN	Report No. 103836 (transfer)
860.1480	Magnitude of residues -	42810314	264	OWN	Report No. 103836-1 (transfer)

Signature



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USA

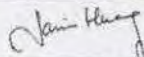
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	meat/milk/poultry/egg				
860.1480	Magnitude of residues - meat/milk/poultry/egg	43143206	264	OWN	Report No. 103833-1 (cattle)
860.1480	Magnitude of residues - meat/milk/poultry/egg	43143207	264	OWN	Report No. 103832-1 (poultry)
860.1500	Magnitude of residue - crop field trials	42556129	264	OWN	Report No. 103824 (cotton)
860.1500	Magnitude of residue - crop field trials	42556131	264	OWN	Report No. 103235 (potato)
860.1500	Magnitude of residue - crop field trials	42556133	264	OWN	Report No. 103234 (apples)
860.1500	Magnitude of residue - crop field trials	42767801	264	OWN	Report No. 103234-1 (apples)
860.1500	Magnitude of residue - crop field trials	42767802	264	OWN	Report No. 103824-1 (cotton)
860.1500	Magnitude of residue - crop field trials	42810301	264	OWN	Report No. 105015 (tomato)
860.1500	Magnitude of residue - crop field trials	42810302	264	OWN	Report No. 103245 (grape)

Signature



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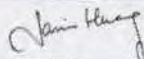
Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	42810303	264	OWN	Report No. 103245-1 (grape)
860.1500	Magnitude of residue - crop field trials	42810304	264	OWN	Report No. 105019 (broccoli)
860.1500	Magnitude of residue - crop field trials	42810305	264	OWN	Report No. 105022 (cauliflower)
860.1500	Magnitude of residue - crop field trials	42810306	264	OWN	Report No. 105040 (cabbage)
860.1500	Magnitude of residue - crop field trials	42810307	264	OWN	Report No. 105164 (lettuce)
860.1500	Magnitude of residue - crop field trials	4281308	264	OWN	Report No. 105165 (Brassica vegetables)
860.1500	Magnitude of residue - crop field trials	42881001	264	OWN	Report No. 105016 (pepper)
860.1500	Magnitude of residue - crop field trials	42995701	264	OWN	Report No. 105011 (mango)
860.1500	Magnitude of residue - crop field trials	43398901	IR-4	PER	Project No. 5369 (hops)
860.1500	Magnitude of residue - crop field trials	43551501	264	OWN	Report No. 106437 (citrus)

Signature



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Applicant=s/Registrant=s Name & Address:

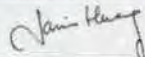
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	43551503	264	OWN	Report No. 106777 (pecan)
860.1500	Magnitude of residue - crop field trials	43600001	264	OWN	Report No. 103824-2 (cotton)
860.1500	Magnitude of residue - crop field trials	43675101	264	OWN	Report No. 106631-1 (tobacco)
860.1500	Magnitude of residue - crop field trials	43801101	264	OWN	Report No. 106789 (pear)
860.1500	Magnitude of residue - crop field trials	43970401	264	OWN	Report No. 103842 (tobacco)
860.1500	Magnitude of residue - crop field trials	44067501	IR-4	PER	Project No. 5181 (cucumber)
860.1500	Magnitude of residue - crop field trials	44067502	IR-4	PER	Project No. 5180 (melon)
860.1500	Magnitude of residue - crop field trials	44067503	IR-4	PER	Project No. 5179 (squash)
860.1500	Magnitude of residue - crop field trials	44067504	IR-4	PER	Project No. A5181 (cucumber)

Signature



Name and Title:  
Jamin Huang, Registration Manager

Date: September 15, 2008



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**1200 Pennsylvania Avenue, N.W.**  
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**DATA MATRIX**

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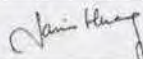
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	44067505	IR-4	PER	Project No. A5180 (melon)
860.1500	Magnitude of residue - crop field trials	44067506	IR-4	PER	Project No. A5179 (squash)
860.1500	Magnitude of residue - crop field trials	44213101	264	OWN	Report No. 107563 (spinach)
860.1500	Magnitude of residue - crop field trials	44438101	264	OWN	Report No. 107126 (celery))
860.1500	Magnitude of residue - crop field trials	44438102	264	OWN	Report No. 106662 (citrus)
860.1500	Magnitude of residue - crop field trials	44438103	264	OWN	Report No. 106662-1 (citrus)
860.1500	Magnitude of residue - crop field trials	44438104	264	OWN	Report No. 106437-1 (citrus)
860.1500	Magnitude of residue - crop field trials	44524901	IR-4	PER	Project No. 95-004 (squash)
860.1500	Magnitude of residue - crop field trials	44524902	IR-4	PER	Project No. 95-007 (cucumber)
860.1500	Magnitude of residue - crop field trials	44524903	IR-4	PER	Project No. 95-006 (cantaloupe)

Signature



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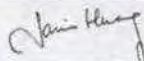
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	44815601	264	OWN	Report No. 108805 (grape)
860.1500	Magnitude of residue - crop field trials	44951601	264	OWN	Report No. 108731 (banana)
860.1500	Magnitude of residue - crop field trials	44982301	264	OWN	Report No. 108847 (potato)
860.1500	Magnitude of residue - crop field trials	45036801	IR-4	PER	Project No. 05477 (succulent beans)
860.1500	Magnitude of residue - crop field trials	45046401	IR-4	PER	Project No. 0620.95-MD03 (lima beans)
860.1500	Magnitude of residue - crop field trials	45194301	IR-4	PER	Project No. 05745 (cranberry)
860.1500	Magnitude of residue - crop field trials	45228401	IR-4	PER	Project No. 0622.97-CA62 (artichoke)
860.1500	Magnitude of residue - crop field trials	45349501	IR-4	PER	Project No. 06307 (carrot)
860.1500	Magnitude of residue - crop field trials	45433801	264	OWN	Report No. 110753 (cucumber)

Signature



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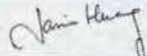
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	45433802	264	OWN	Report No. 110754 (cucumber, tomato, pepper)
860.1500	Magnitude of residue - crop field trials	45433803	264	OWN	Report No. 110755 (cucumber)
860.1500	Magnitude of residue - crop field trials	45433804	264	OWN	Report No. 110756 (tomato)
860.1500	Magnitude of residue - crop field trials	45433805	264	OWN	Report No. 110757 (cucumber)
860.1500	Magnitude of residue - crop field trials	45433806	264	OWN	Report No. 110758 (tomato)
860.1500	Magnitude of residue - crop field trials	45433807	264	OWN	Report No. 110759 (pepper)
860.1500	Magnitude of residue - crop field trials	45547001	IR-4	PER	Project No. 06449 (passion fruit)
860.1500	Magnitude of residue - crop field trials	45580401	IR-4	PER	Project No. 06398 (pea)
860.1500	Magnitude of residue - crop field trials	45587101	IR-4	PER	Project No. 06450 (mamey sapote)
860.1500	Magnitude of residue - crop field trials	45597901	IR-4	PER	Project No. 06305 (garden beet)

Signature



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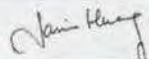
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

	trials				
860.1500	Magnitude of residue - crop field trials	45616301	IR-4	PER	Project No. 06260 (strawberry)
860.1500	Magnitude of residue - crop field trials	45616401	IR-4	PER	Project No. 06528 (dry bean)
860.1500	Magnitude of residue - crop field trials	45619701	IR-4	PER	Project No. 06399 (cherry)
860.1500	Magnitude of residue - crop field trials	45619702	IR-4	PER	Project No. 06399 (peach)
860.1500	Magnitude of residue - crop field trials	45619703	264	OWN	Report No. 109238 (peach)
860.1500	Magnitude of residue - crop field trials	45619704	IR-4	PER	Project No. 07279 (plum)
860.1500	Magnitude of residue - crop field trials	45647801	IR-4	PER	Project No. 07738 (guava)
860.1500	Magnitude of residue - crop field trials	45757801	IR-4	PER	Project No. 06308( Radish)
860.1500	Magnitude of residue - crop field trials	45795701	IR-4	PER	Project No. 07351 (papaya)

Signature



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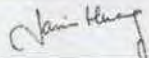
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1500	Magnitude of residue - crop field trials	45795701	IR-4	PER	Project No. A07351 (papaya)
860.1500	Magnitude of residue - crop field trials	45826301	IR-4	PER	Project No. A07523 (raspberry)
860.1500	Magnitude of residue - crop field trials	46025801	IR-4	PER	Project No. 97/001 (sunflower)
860.1500	Magnitude of residue - crop field trials	46031401	IR-4	PER	Project No. A06993 (sugar apple)
860.1500	Magnitude of residue - crop field trials	46188201	IR-4	PER	Project No. 07099 (avocado)
860.1520	Processing Study	42556130	264	OWN	Report No. 103246 (cotton)
860.1520	Processing Study	42556132	264	OWN	Report No. 103238 (potato)
860.1520	Processing Study	42556134	264	OWN	Report No. 103236 (apples)
860.1520	Processing Study	42767803	264	OWN	Report No. 103246-1 (cotton)
860.1520	Processing Study	42810309	264	OWN	Report No. 105024 (tomato)
860.1520	Processing Study	42810310	264	OWN	Report No. 103839 (grape)
860.1520	Processing Study	43490301	264	OWN	Report No. 106651 (tomato)

Signature



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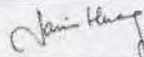
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

860.1520	Processing Study	43551502	264	OWN	Report No. 106771 (orange)
860.1520	Processing Study	44438105	264	OWN	Report No. 106771-1 (orange)
860.1520	Processing Study	46025801	IR-4	PER	Project No. 97/001 (sunflower)
860.1850	Confined rotational crop	42556104	264	OWN	Report No. 103812
860.1900	Field rotational crop	43245901	264	OWN	Report No. 105153
860.1900	Field rotational crop	44063701	264	OWN	Report No. 107133
<b>Toxicology, Section 158.340</b>					
870.1100	Acute oral toxicity rat	42055331	264	OWN	Report No. 100040 (TGAI)
870.1100	Acute oral toxicity rat	42256313	264	OWN	Report No. 100010 (2 F)
870.1100	Acute oral toxicity rat	43428201	264	OWN	Report No. 106380 (1.6 F)
870.1200	Acute dermal toxicity, rat/rabbit	42055332	264	OWN	Report No. 100041 (TGAI)
870.1200	Acute dermal toxicity, rat/rabbit	42256315	264	OWN	Report No. 100002 (2 F)
870.1200	Acute dermal toxicity, rat/rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.1300	Acute inhalation toxicity, rat	42055333	264	OWN	Report No. 99806 (TGAI)
870.1300	Acute inhalation toxicity, rat	42286101	264	OWN	Report No. 99806-1 (TGAI)

Signature



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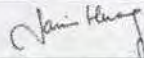
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.1300	Acute inhalation toxicity, rat	42256317	264	OWN	Report No. 100012 (2 F)
870.1300	Acute inhalation toxicity, rat	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2400	Primary eye irritation - rabbit	42055334	264	OWN	Report No. 99679 (TGAI)
870.2400	Primary eye irritation - rabbit	42256319	264	OWN	Report No. 99815 (2 F)
870.2400	Primary eye irritation - rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2500	Primary dermal irritation - rabbit	42055335	264	OWN	Report No. 99804 (TGAI)
870.2500	Primary dermal irritation - rabbit	42256321	264	OWN	Report No. 99816 (2 F)
870.2500	Primary dermal irritation - rabbit	43428201	264	OWN	Report No. 106380 (1.6 F)
870.2600	Dermal sensitization - guinea pig	42055336	264	OWN	Report No. 99800 (TGAI)
870.2600	Dermal sensitization - guinea pig	42256323	264	OWN	Report No. 100003 (2 F)
870.2600	Dermal sensitization - guinea pig	43428201	264	OWN	Report No. 106380 (1.6 F)
870.3100	90-day feeding - rodent	42256327	264	OWN	Report No. 100036
870.3150	90-day feeding - non-rodent	42256328	264	OWN	Report No. 100176
870.3200	21-day dermal - rabbit/rat	42256329	264	OWN	Report No. 100688
870.3700	Developmental toxicity - rat	42256338	264	OWN	Report No. 98571

Signature



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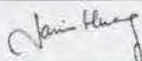
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.3700	Developmental toxicity - rabbit	42256339	264	OWN	Report No. 98572
870.3800	Two generation reproduction - rat	42256340	264	OWN	Report No. 100647
870.4100	Chronic feeding toxicity - rodent	42256331	264	OWN	Report No. 100652
870.4100	Chronic feeding toxicity - rodent	42256332	264	OWN	Report No. 101931
870.4100	Chronic feeding toxicity - rodent	42256333	264	OWN	Report No. 102658
870.4100	Chronic feeding toxicity - rodent	42256334	264	OWN	Report No. 99672
870.4100	Chronic feeding toxicity - non-rodent	42273002	264	OWN	Report No. 100015
870.4200	Oncogenicity - rat	42256331	264	OWN	Report No. 100652
870.4200	Oncogenicity - rat	42256332	264	OWN	Report No. 101931
870.4200	Oncogenicity - rat	42256333	264	OWN	Report No. 102658
870.4200	Oncogenicity - rat	42256334	264	OWN	Report No. 99672
870.4200	Oncogenicity - rat	42256335	264	OWN	Report No. 100693
870.4200	Oncogenicity - rat	42256336	264	OWN	Report No. 101929
870.4200	Oncogenicity - rat	42256337	264	OWN	Report No. 99808
870.5100	Gene mutation (ames test)	42256341	264	OWN	Report No. 101276

Signature



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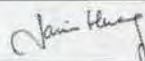
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RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

870.5100	Gene mutation (ames test)	42256342	264	OWN	Report No. 98584
870.5100	Gene mutation (ames test)	42256343	264	OWN	Report No. 98570
870.5375	Structural chromosomal aberration	42256344	264	OWN	Report No. 100021
870.5375	Structural chromosomal aberration	42256345	264	OWN	Report No. 99262
870.5375	Structural chromosomal aberration	42256346	264	OWN	Report No. 99257
870.5375	Structural chromosomal aberration	42256347	264	OWN	Report No. 102652
870.5375	Structural chromosomal aberration	42256348	264	OWN	Report No. 102654
870.5375	Structural chromosomal aberration	42256349	264	OWN	Report No. 102655
870.5395	Micronucleus test	42256350	264	OWN	Report No. 99676
870.5395	Micronucleus test	42256351	264	OWN	Report No. 101275
870.5550	Unscheduled DNA synthesis	42256352	264	OWN	Report No. 98573
870.5550	Unscheduled DNA synthesis	42256353	264	OWN	Report No. 102653
870.6200	Acute neurotoxicity	43170301	264	OWN	Report No. 106348
870.6200	Acute neurotoxicity	43285801	264	OWN	Report No. 106348-1
870.6200	90 day neurotoxicity - mammal	43286401	264	OWN	Report No. 106356

Signature



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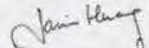
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Date: September 15, 2008	EPA Reg. No./File Symbol: 264-RNIR	Page 31 of 31
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive RTP, NC 27709 USA	Product(s): Sepresto 75 WS	
Ingredient: Clothianidin + Imidacloprid		

870.6300	Developmental neurotoxicity	45537501	264	OWN	Report no. 110245
870.7485	General metabolism	42256354	264	OWN	Report No. 101999
870.7485	General metabolism	42256355	264	OWN	Report No. 87264
870.7485	General metabolism	42256356	264	OWN	Report No. 87265
870.7485	General metabolism	42256357	264	OWN	Report No. 102617
<b>Reentry Protection, Section 158.390</b>					
875 Group A and B	Mixer/loader/applicator exposure	42256386	264	OWN	Report No. 94273
875.2100	Foliar dislodgeable exposure	44957601	264	OWN	Report No. 109318
<b>Spray Drift, Section 158.440</b>					
201-1	Droplet size spectrum	43766502	SDTF	PER	Report No. A92/004
<b>Applicator Exposure</b>					
None	Worker Exposure study	42256386	264	OWN	Report No. 94273
<b>Miscellaneous Studies</b>	<b>Supplemental</b>				
None	Benefits Reports	42620801	264	OWN	Report No. 103881
None	Benefits Reports	42810315	264	OWN	Report No. 103878

Signature 	Name and Title: Jamin Huang, Registration Manager	Date: September 15, 2008
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1200 Pennsylvania Avenue, N.W.  
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DATA MATRIX

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 32 of 32

Applicant=s/Registrant=s Name & Address:

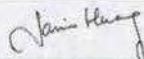
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

None	Dietary Analysis	44790101	264	OWN	Report No. 108790
None	Dietary Analysis	44886001	264	OWN	Report No. 109180
None	Dietary Analysis	44886002	264	OWN	Report No. 109180-1

Signature



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Jamin Huang, Registration Manager

Date: September 15, 2008



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Page 1 of 1

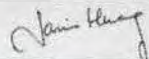
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

Guideline Reference Number	Guideline Study Name	MRID Number	Submitter	Status	Note
Sepresto 75 WS					
			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	
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			Bayer Cropscience	OWN	
			Bayer Cropscience	OWN	

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Page 2 of 2

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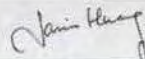
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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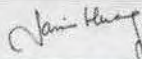
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
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Ingredient: Clothianidin + Imidacloprid

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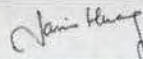
Bayer CropScience, 2 T.W. Alexander Drive  
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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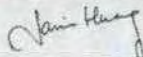
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
 RTP, NC 27709  
 USA

Product(s):  
 Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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	Bayer Cropscience	OWN	
Imidacloprid			
	264	OWN	
	264	OWN	
	264	OWN	

Signature



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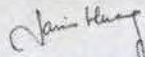
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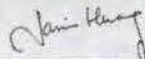
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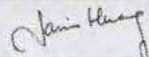
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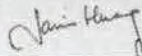
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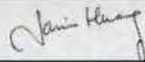
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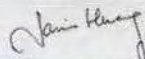
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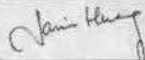
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Page 13 of 13

Applicant/s/Registrant/s Name & Address:

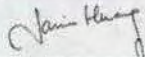
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EPA Reg. No./File Symbol: 264-RNIR

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Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
 RTP, NC 27709  
 USA

Product(s):  
 Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
264	OWN
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264	OWN
264	OWN
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264	OWN
264	OWN

Signature

*Jamin Huang*

Name and Title:  
 Jamin Huang, Registration Manager

Date: September 15, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

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DATA MATRIX

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 15 of 15

Applicant=s/Registrant=s Name & Address:

Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
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264	OWN
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264	OWN
264	OWN

Signature

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DATA MATRIX

Date: September 15, 2008

EPA Reg. No./File Symbol: 264-RNIR

Page 16 of 16

Applicant=s/Registrant=s Name & Address:

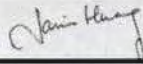
Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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264	OWN
264	OWN
264	OWN
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Signature



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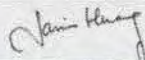
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
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IR-4	PER
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264	OWN

Signature



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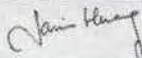
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Product(s):  
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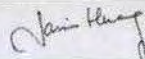
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Applicant=s/Registrant=s Name & Address:

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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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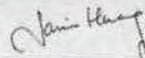
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
264	OWN
264	OWN
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264	OWN
264	OWN
264	OWN
264	OWN
IR-4	PER
IR-4	PER
IR-4	PER

Signature



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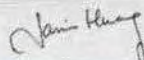
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 RTP, NC 27709  
 USA

Product(s):  
 Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
IR-4	PER
IR-4	PER
264	OWN
264	OWN
264	OWN
264	OWN
264	OWN
IR-4	PER

Signature



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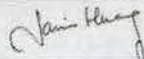
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
IR-4	PER
264	OWN
264	OWN
264	OWN
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER

Signature



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RTP, NC 27709  
USA

Product(s):

Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

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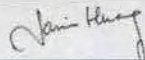
IR-4

PER

IR-4

PER

Signature



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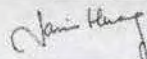
Bayer CropScience, 2 T.W. Alexander Drive  
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USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
264	OWN
IR-4	PER
IR-4	PER
IR-4	PER

Signature



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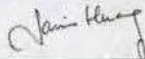
Applicant=s/Registrant=s Name & Address: Bayer CropScience, 2 T.W. Alexander Drive  
RTP, NC 27709  
USA

Product(s):  
Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
IR-4	PER
264	OWN
264	OWN
264	OWN
264	OWN

Signature



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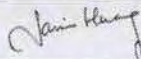
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Signature



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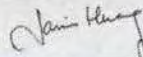
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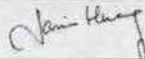
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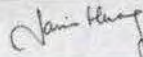
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Applicant=s/Registrant=s Name & Address:

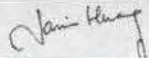
Bayer CropScience, 2 T.W. Alexander Drive  
 RTP, NC 27709  
 USA

Product(s):  
 Sepresto 75 WS

Ingredient: Clothianidin + Imidacloprid

264	OWN
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SDTF	PER
264	OWN

Signature



Name and Title:

Jamin Huang, Registration Manager

Date: September 15, 2008



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
1200 Pennsylvania Avenue, N.W.  
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060; 2070-0057;  
2070-0107; 2070-0122; 2070-01634

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Date: September 15, 2008

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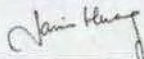
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